2018 Annual Report

Cancer Prevention & Research Institute of Texas

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REPORT FROM THE CHIEF EXECUTIVE OFFICER

Despite advances, cancer remains the leading cause of death for Texans under the age of 85, with 120 Texans dying from cancer every day. More Texas children and adolescents die from cancer than any other disease; cancer will kill 217 children and adolescents in Texas this year. Although the tragic emotional and physical toll of cancer is incalculable, in purely economic terms cancer cost the state $40.3 billion in direct medical costs and mortality losses in 2018. This is $1.5 billion more than the state's cost in 2017. Considering Texas' emerging demographics and growing population, the state's cost of cancer is unlikely to decline unless Texas makes significant and sustainable changes now.

In 2018 CPRIT built on the momentum that started eleven years ago with Texas' historic decision to invest $3 billion for cancer research and prevention. Texas' pledge is the only commitment of its kind and scope in the United States. CPRIT is improving Texas' national standing in both cancer research and the biomedical industry. Key metrics show that CPRIT's investments in the life science infrastructure are transforming Texas, paving the way for the state to become a major biotechnology hub.

CPRIT is often asked the question, "When are you going to cure cancer?" We are curing cancer now, one discovery at a time. Our grantees are making prevention and cures for cancer possible with every advancement. CPRIT's investments connect universities, researchers, physicians, companies, hospitals, and clinics across Texas forming a critical infrastructure of distinguished cancer-fighting talent. CPRIT is proud to be part of this connectivity. Projects we fund have created high quality jobs, supported critical lab infrastructure assets, and along the way, helped thousands of cancer patients extend their lives. CPRIT is delivering promised benefits today. Through CPRIT and in thousands of personal ways, *Texans Conquer Cancer*. Three advances resulting from CPRIT funding illustrate CPRIT's contribution to this process. We discuss other milestones and key accomplishments for CPRIT grant recipients throughout this report.

- Texans with melanoma, lung cancer, bladder cancer, lymphoma, leukemia, and osteosarcomas have access to CPRIT-sponsored clinical research of novel immunotherapies. These powerful new cancer therapies include the immune checkpoint inhibitors discovered by CPRIT Scholar and 2018 Nobel Laureate Dr. James Allison of The University of Texas MD Anderson Cancer Center. More than 100 clinical trials and studies supported by CPRIT are underway, with 13,400 patients enrolled.

- A team of scientists, surgeons, and engineers from The University of Texas at Austin, Baylor College of Medicine, and The University of Texas MD Anderson Cancer Center are developing a new handheld device that rapidly and accurately identifies cancerous tissue during surgery. The "MasSpec Pen" is an innovative instrument that promises to give surgeons precise diagnostic information about what tissue to cut or preserve as they perform surgery, helping to improve treatment and reduce the chances of cancer recurrence. It delivers results in about 10 seconds – 150 times faster than existing technology. The MacArthur Foundation recently recognized the game-changing potential of the MasSpec Pen, bestowing CPRIT grantee Dr. Livia Eberlin at The University of Texas at Austin with a 2018 MacArthur "Genius" Award for her work leading the MasSpec Pen team and developing pioneering mass spectrometry technologies.

- CPRIT-funded company Cell Medica is developing a novel process to modify the body's immune cells to target and kill cancer cells while leaving normal healthy tissue unharmed. The technology involves Epstein-Barr virus targeted T-cells and is showing exciting results in Phase II clinical studies in Texas. Cell Medica is working in partnership with Baylor College of Medicine under an exclusive license and co-development agreement. This collaboration will generate many new products for Cell Medica's pipeline.

The successes and progress outlined in this report provide a foundation for the future; Texas can do much more. We are nearing a critical juncture. Through fiscal year 2018, CPRIT has awarded $2.15 billion, 76% of the funds available for awards in its constitutional authorization. CPRIT has $677 million remaining to award at the end of fiscal year 2018. Beginning in fiscal year 2020, CPRIT will not have enough bond funds to support cancer research and prevention activities at current levels. Unless the legislature acts, CPRIT will cease awarding grants after August 31, 2021. What will the state's cancer landscape look like if CPRIT sunsets in 2023?

An independent economist identifies ten years of significant negative economic consequences if the state does not sustain CPRIT's programs. Even when one considers other potential uses for CPRIT's state funding, the expected gross cumulative ten-year effect of not extending its programs results in a $141.7 billion loss in gross economic product and some 1,207,000 person-years of employment. These include $10.2 billion lost to state and local governments over the same period. This report details the negative economic consequences of not extending CPRIT beyond its current authorization as well as the significant contributions CPRIT's activities play in the state's economy. CPRIT more than pays for itself in fiscal terms. You can judge on your own what it means in human terms.

Shortly after the announcement that he had won the 2018 Nobel Prize in Medicine, CPRIT Scholar Jim Allison was asked, "So what now?" His response? "Keep working and try to do it better." So it goes with CPRIT. We need to keep working, try to do it better, and based on what we have learned during our successful experience, explore *new opportunities* to take Texas' fight against cancer to greater levels.

Reflecting on 2018, the Institute is excited about the foundation it has laid in cancer research and prevention. We see much good to do on the horizon. Texas Comptroller of Public Accounts Glenn Hegar, noting Texas' long history of embracing new industries from the invention of the integrated circuit to the West Texas wind farms, recently called for the state to embrace the opportunity to make Texas the "third coast" for biotech. CPRIT is integral to this endeavor.

When the Texas Legislature created CPRIT, it tasked the agency with creating and accelerating innovation in cancer prevention, treatments, and cures. Through CPRIT's investments in research capabilities, we are expanding the state's life sciences infrastructure and providing life-

extending results now. The pages that follow reflect that CPRIT and the state have real momentum with measurable results and new opportunities exist for Texas' historical initiative to fight cancer.

CPRIT is grateful for those who are working every day to reduce the burden of cancer across the state. Their dedication and support inspire us in our efforts to serve Texans. On behalf of the CPRIT Oversight Committee and the Institute's staff, we appreciated the opportunity to make 2018 another productive year. We look forward to new opportunities to fulfill our mission to improve the health and lives of our fellow Texans.

REAL MOMENTUM ▶ MEASURABLE RESULTS

CPRIT WAS ESTABLISHED TO:

1. INVEST IN TEXAS RESEARCH CAPABILITIES

Attract, create and expand research capabilities in higher education

- **159 stellar researchers** and their labs recruited to Texas institutions
- **3 NCI** comprehensive cancer centers – previously only MD Anderson
- **$901 million** in direct follow-on funding to CPRIT academic grantees
- **43 core** facilities to provide access to cutting-edge shared technology through capital instrumentation and technical expertise

2. CREATE AND EXPAND TEXAS LIFE SCIENCE INFRASTRUCTURE

Attract, create and expand the capabilities of private entities and create high-quality new jobs

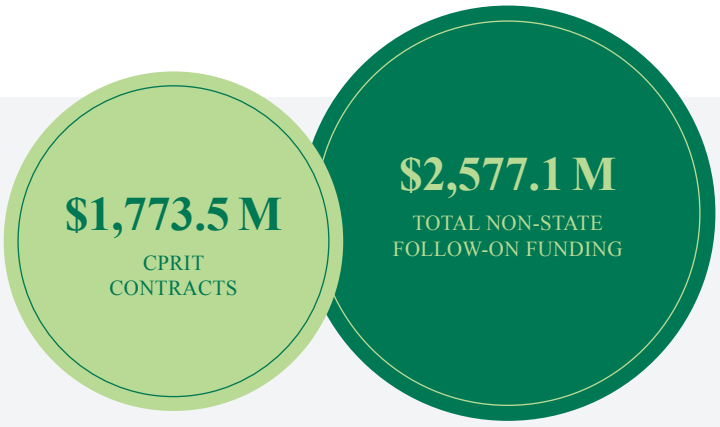
- **30 biotech** companies started, expanded, or brought to Texas
- CPRIT awards increase VC biotech investment in Texas by **11 percent**
- **$1.61 B** (greater than 4 to 1) direct follow-on funding to CPRIT companies
- **$1.38 B** in 2018 total expenditures
- **$57 million** annual state and local tax collections
- **Over 10,000** permanent jobs created in 2017

3. EXPEDITE INNOVATION IN CANCER PREVENTION AND CURES

Expedite innovation in research and enhance the potential of breakthroughs in prevention and cures

- 13,318 patients in 108 **clinical trials or studies**
- **13,277** cancer precursors and **3,364** cancers detected
- Nationally recognized teams and centers in immunotherapy and childhood cancers
- **Over 4,200** published or pending findings & **246** patent applications

Follow-on funds **($2.6 Billion)** for the two research programs **($1.8 Billion)**, exceeding contracted awards by **$804 M**



Last Updated: August 31, 2018

Real Momentum, Measurable Results:
Investing in Texas Research Capabilities

159 Cancer Researchers and their labs recruited to Texas

With CPRIT funding, Texas is well on its way to having the finest cluster of cancer researchers in the world.

Jim Allison, Ph.D.

Recruitment to The University of Texas MD Anderson Cancer Center from Memorial Sloan-Kettering Cancer Center

Jim Allison has spent a distinguished career studying the regulation of T cell responses and pioneering new strategies for cancer immunotherapy. Dr. Allison showed that CTLA-4 acts as an inhibitory molecule to restrict T-cell responses and was the first to show that antibody blockade CTLA-4 could lead to enhanced anti-tumor immune responses and tumor rejection. He, along with Tasuku Honjo, was jointly awarded the Nobel Prize in Physiology or Medicine in 2018 for their discovery of cancer therapy by inhibition of negative immune regulation.

S. Gail Eckhardt, M.D. FASCO

Recruitment to the LIVESTRONG Cancer Institutes, Dell Medical School at The University of Texas at Austin from the University of Colorado, Denver

Re-envisioning cancer care with the patient at the center is Dr. Eckhardt's mission as the inaugural director of the LIVESTRONG Cancer Institutes. A physician-scientist, she is internationally recognized as a leader in collaborative preclinical and early clinical translational cancer research.

Kevin Pruitt, Ph.D.

Recruitment to the Texas Tech University Health Sciences Center from Louisiana State University Health Sciences Center

Blocking estrogen production is one way of treating breast cancers, but also often produces side effects like cognitive deficits or osteoporosis in patients. Dr. Pruitt's approach is to look further upstream for ways to block a breast tumor's estrogen production. If he's successful, a therapy to shut down the unhealthy, life-prolonging production of estrogen in tumor cells wouldn't affect the life-sustaining estrogen in normal tissues.

Ning Jiang, Ph.D.

Recruitment to The University of Texas at Austin from Stanford University

Dr. Jiang has developed a method of high-throughput screening to see how well T-cell receptors on individual T cells bind to different antigens. Jiang can now isolate T cells, find out how well they bind to antigens, and sequence the T-cell receptor genes—all in a process that is 1000 times faster, completing 50-60 T cells in a single day. Previously, it would have taken months, if not years, to complete a single screen.

Carlos L. Arteaga, M.D.

Recruited to The University of Texas Southwestern Medical Center from the Vanderbilt University Medical Center.

Internationally renowned breast cancer researcher and physician, Dr. Arteaga is working to improve breast cancer patients' chances of beating the disease for good. His research focuses on identifying the causes of drug resistance and employing combination therapies to circumvent it.

Cassian Yee, M.D.

Recruitment to The University of Texas MD Anderson Cancer Center from the Fred Hutchinson Cancer Research Center.

Harnessing a patient's own immune system to attack and defeat cancer may be one of the most promising cancer therapies. Dr. Yee's research involves isolating normal white blood cells—killer T cells—from a patient's own blood and finding the rare ones that have the ability to recognize and attack the cancer cells.

Last Updated: August 31, 2018

Cancer Prevention & Research Institute of Texas

43 Core Facilities supported to ensure cutting-edge research

CPRIT's investment in core facilities fosters collaboration among cancer researchers and provides shared access to current technology.

Funda Meric-Bernstam, M.D.

The University of Texas MD Anderson Cancer Center

The Precision Oncology Decision Support Core assists clinicians in managing the results of genomic testing of patients with advanced cancer and to select and effectively implement gnomically-informed therapy. The core supports an online portal that allows treating physicians to request molecular annotation of their patient's tumor molecular profile. It also supports an effort that issues proactive and individualized trial alerts to treating physicians for MD Anderson patients who underwent molecular testing.

Kevin Dalby, Ph.D.

The University of Texas at Austin

The Targeted Therapeutic Drug Discovery & Development Program provides Texas cancer researchers with access to cutting-edge technologies and expertise to enable the translation of their research into new treatments for cancers. The core provides specialized resources and experiences in the early phase of drug development efforts including validation of good molecular targets and the design and development of chemical probes that effectively hit those targets for pre-clinical studies. The core is a component of the Gulf Coast Consortia where access to medicinal chemistry, structural biology and pharmacokinetic expertise can efficiently drive the progression of hits to pre-clinical candidates.

Michael Scheurer, Ph.D., M.P.H.

Baylor College of Medicine

The Adolescent and Childhood Cancer Epidemiology and Susceptibility Service for ACCESS- Texas supports the identification of novel genetic risk factors and gene-environment interactions important in understanding cancer susceptibility among children and adolescents, particularly among the diverse patient population in Texas. The core has established collaborations with childhood cancer providers across Texas with the goal to collect and bank biospecimens for family-based studies of genetic risk factors, studies of environmental risk factors, gene-environment interaction studies, and studies of treatment-related toxicities and late effects.

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Cancer Prevention & Research Institute of Texas

Real Momentum, Measurable Results: Investing in Texas Research Capabilities

Centers of Excellence Catalyzed by CPRIT

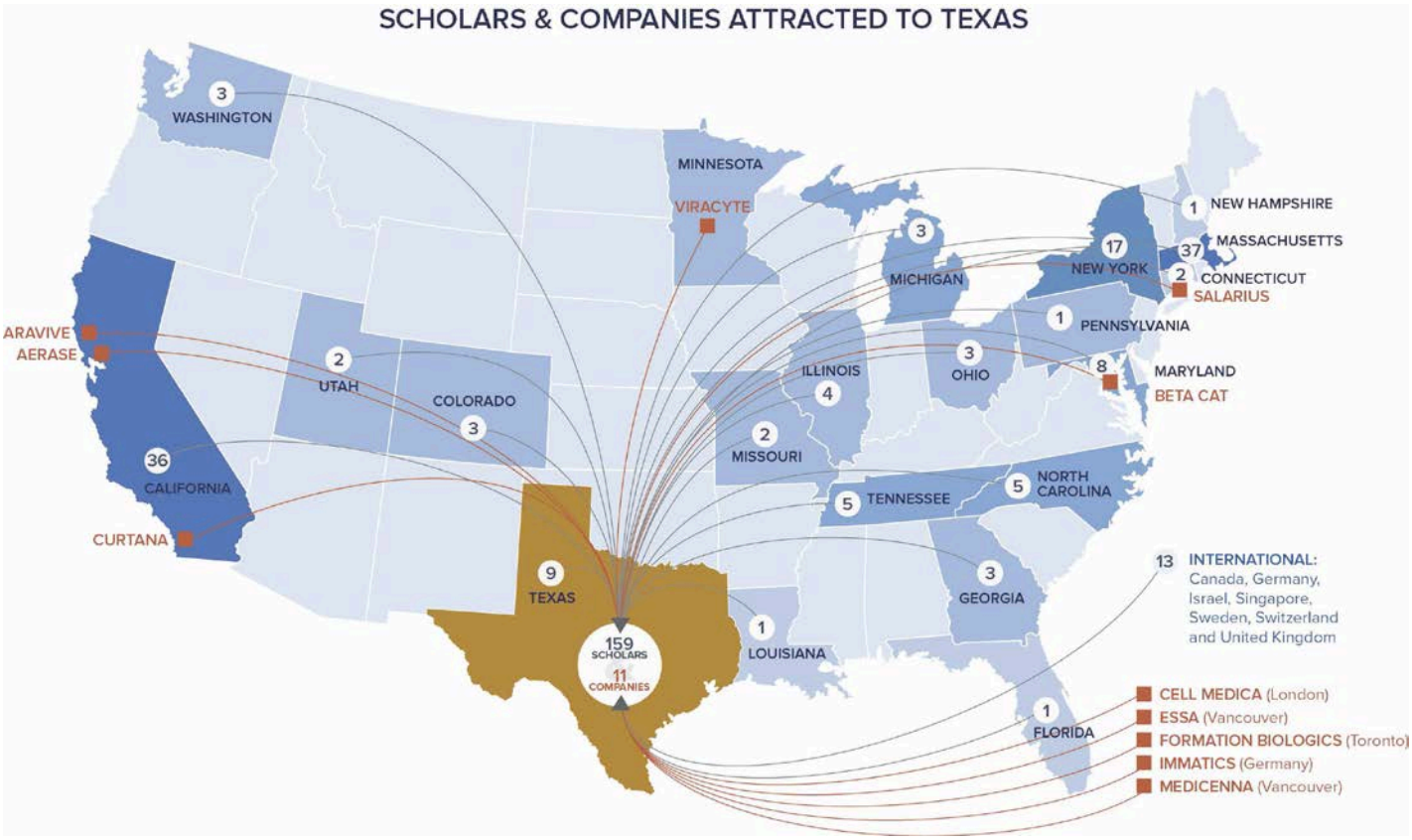
RICE → Nicolaou Research Accelerator collaboration with AbbVie

THE UNIVERSITY OF TEXAS MD Anderson Cancer Center Making Cancer History® → SU2C "Immunology Dream Team" & Parker Institute Center

Baylor College of Medicine → NIH Proteogenomic Translational Research Centers

UT Southwestern Medical Center Kidney Cancer Program → NCI Kidney Cancer SPORE

Real Momentum, Measurable Results: Creating and Expanding Texas Life Science Infrastructure



22 Product Development research grantees established Texas institution partnerships

CPRIT is fortifying its place as a leading cancer fighting ecosystem with more than $380 million invested in product development research grants.

Immatics U.S. Inc. and The University of Texas MD Anderson Cancer Center:
Immatics U.S. Inc. enrolled initial patients in a Phase I trial at **MD Anderson** of an investigational immunotherapy technology (IMA201) to genetically engineer a patient's own T-cells to attack solid tumors. Immatics also announced the completion of its Series E financing, raising $58 million to support ongoing clinical studies and further develop its pipeline of novel cancer immunotherapies.

Nexeon MedSystems, Inc., The University of Texas Southwestern Medical Center, and The University of Texas at Dallas:
Surgical resection and radiotherapy are used frequently in the treatment of prostate, cervical, and rectal cancers. While they can be life-saving therapies, these procedures often burden cancer survivors with secondary conditions such as overactive bladder (OAB). (Nexeon, formerly Rosellini Scientific) in collaboration with **UT Southwestern** and through the **UT Dallas** incubator program, is developing a small, implantable neurostimulation device to restore bladder function and improve quality of life for patients suffering from OAB due to cancer therapy.

OncoNano Medicine, The University of Texas Southwestern Medical Center, and The University of Texas MD Anderson Cancer Center:
OncoNano Medicine, a Dallas-based **UT Southwestern** spinout, is developing nanotechnology-enabled fluorescent probes to help surgeons excise tumors. Surgery is a major mode of cancer treatment and a major challenge is in differentiating tumors from healthy tissue. OncoNano will operate in **UT Southwestern's** incubator. OncoNano recently received Fast Track Designation for its intraoperative imaging agent ONM-100 to detect tumors and metastatic lymph nodes that often go undetected during surgery.

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Real Momentum, Measurable Results:
Expediting Innovation in Cancer Prevention and Cures

108 New Clinical Studies

CPRIT funding has resulted in the enrollment of 13,318 patients in clinical studies.

Robert Timmerman, M.D.
The University of Texas Southwestern Medical Center

Hypofractionated Image-Guided Radiation Therapy (IGRT) in Patients With Stage II-III Non-Small Cell Lung Cancer (Phase III study)

This study is designed to determine whether an accelerated course of hypofractionated radiation therapy with daily image guidance and motion assessment/control will allow more effective treatment of poor performance status patients with stage II-III Non-Small Cell Lung Cancer, who would benefit from local therapy compared to standard radiation.

For More Information: clinicaltrials.gov/ct2

Aeglea Biotherapeutics, Inc.

A Multiple Dose, Dose Escalation Trial of AEB1102 in Patients With AML or MDS and A Multiple Dose, Dose Escalation Trial of AEB1102 in Patients with Advanced Solid Tumors.

These two Phase 1 clinical trials are investigating the therapeutic potential of a novel enzyme therapy, AEB1102, to treat Acute Myeloid Leukemia, Myelodysplastic Syndrome, and advanced solid tumors. AEB1102 was originally developed by Dr. Georgiou and his team at theUniversity of Texas at Austin. These multicenter trials include two Texas sites—Baylor Scott & White and The University of Texas Southwestern Cancer Center.

For More Information: clinicaltrials.gov/ct2

Rajiv Chopra, Ph.D. and Ted Laetsch, M.D.
The University of Texas Southwestern Medical Center

HIFU Hyperthermia With Liposomal Doxorubicin (DOXIL) for Relapsed or Refractory Pediatric and Young Adult Solid Tumors (Phase 1 study)

High-Intensity Focused Ultrasound (HIFU) is a form of image-guided therapy capable of noninvasive tissue ablation and drug delivery. Similar to the concentration of light energy to a focal point using a lens, HIFU can concentrate acoustic energy within the body to a region of a few millimeters in dimension. The energy at the focus is sufficient to thermally coagulate tissues—rendering them permanently destroyed—without causing any damage to intervening tissues. Because HIFU is noninvasive and does not involve ionizing radiation, it is very well-suited for use in pediatric medicine.

For More Information: clinicaltrials.gov/ct2

Medicenna Therapeutics, Corp.

Convection-Enhanced Delivery (CED) of MDNA55 in Adults with Recurrent or Progressive Glioblastoma. This Phase 2 clinical trial investigates the efficacy of MDNA55, a targeted immunotherapy, in treating adults with recurrent glioblastoma. In this study, investigators administer MDNA55 directly into brain tumors using a technique known as Convection Enhanced Delivery (CED). The multicenter trial includes two sites in Texas—The University of Texas Southwestern Cancer Center and the Cancer Therapy and Research Center at The University of Texas Health Science Center at San Antonio.

For More Information: clinicaltrials.gov/ct2

Last Updated: August 31, 2018

Cancer Prevention & Research Institute of Texas

Real Momentum, Measurable Results:
Expediting Innovation in Cancer Prevention and Cures

4.7 MILLION
prevention services in Texas

Saving Lives: CPRIT funding has provided prevention services to Texans in all 254 counties.

A total of 2,330,005 education and training services, and 2,422,658 clinical services have been delivered to Texans. According to grantee reports, these projects in the CPRIT portfolio have led to:

204,512 Prevention Vaccinations

21,220 Genetic testing and counseling services

212,364 Tobacco cessation services

20,210 Survivor care services

1,185,141

Screenings and diagnostics for breast, lung, cervical, HPV-related, liver and colorectal cancer. Of these:

- **355,002** recipients had never before been screened;
- **13,277** cancer precursors were detected; and
- **3,364** cancers were detected.

Last Updated: August 31, 2018

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

OPPORTUNITIES

CPRIT is achieving the goals set in state law. Through August 31, 2018, CPRIT has invested $2.15 billion in 1,317 of the best ideas in cancer research, product development and prevention. These investments are building a vibrant life sciences and prevention infrastructure and have enhanced Texas' competitive edge in the global fight against cancer.

From this foundation, the state can expand into new life science opportunities:

- Capitalize on CPRIT's longstanding investments in improving outcomes in childhood cancer; with continued support, Texas is poised to be the world leader in childhood cancer research;
- Create and expand research and treatment capabilities at universities in all regions of the state;
- Expand clinical trial options to more people by reducing institutional and patient barriers to trials;
- Increase the number and breadth of Collaborative Action Programs (CAPs) that targets Texas-centric needs in cancer research and prevention. The CPRIT-initiated liver cancer CAP is addressing liver cancer, which Texas ranks first among states in incidence rate;
- Grow and enhance the coalitions and networks delivering cancer prevention services by providing infrastructure to support them;
- Take advantage of the pipeline of novel cancer diagnostic and treatment discoveries at Texas universities by supporting the transition of early stage development in the growing number of Texas-based companies;
- Double the number of NCI Comprehensive Cancer Centers and elevate Texas institutions' standing in prominent national reviews such as the *US News and World Report's* rankings through continued investment in research capacity, access to cutting-edge technology, and recruiting preeminent experts and the next generation of scientific leaders to Texas;
- Co-invest with established bio-tech venture capital firms in promising Texas-based companies, sharing the risks and rewards equally.

The Cost of Cancer in Texas and The State's Response

THE COST OF CANCER IN TEXAS AND THE STATE'S RESPONSE

The American Cancer Society estimates that more than 121,800 Texans will be diagnosed with cancer in 2018, with 41,390 dying of the disease. Cancer is the leading cause of death for people younger than 85 and will surpass heart disease as the overall leading cause of death within this decade. One in three men and women will receive a cancer diagnosis in their lifetimes. Improvements in treatment and earlier detection mean that the number of people diagnosed and living with cancer in the state will continue to increase as Texas' population grows and ages.

Cost of Cancer to Texas

According to the 2018 report *An Economic Assessment of the Cost of Cancer in Texas and the Benefits of the Cancer Prevention and Research Institute of Texas (CPRIT) and its Programs*, by The Perryman Group, direct medical costs and morbidity and mortality losses in the state totaled $40.3 billion in 2018, up from $38.7 billion in 2017 and $34.9 billion two years ago.

Each year cancer costs the Texas economy:

- $212.2 billion in reduced annual spending;
- $104.6 billion in output losses annually; and
- 1,064,595 lost jobs from cancer treatment, morbidity and mortality, and the associated spillover effects.

Texas expends more than $1.1 billion in state funds annually in cancer-related expenses.

Initiative/Organization	**FY 2017 Cancer-Related Expenditures (most recent data available)**
Children's Health Insurance Program	$10.6 million
Texas Medicaid	$216.6 million
Teacher Retirement System of Texas	$571.1 million
Employees Retirement System of Texas	$358 million

National Cancer Funding

The National Cancer Institute (NCI) is the principal federal agency for cancer research and training. The NCI continued a three-year trend in increased funding with its 2017 budget totaling $5.69 billion, $454 million (8.7%) more than budgeted for 2016.

The state increased the amount of NCI funding it received in 2017 and 2018, attracting $240 million each of the past two years. While the upward movement in NCI funding is encouraging, Texas must still mitigate the historical fact that it lags other states in cancer research funding. Texas has 8.4% of the US population and 9.4% of the national gross domestic product. However, on a five-year rolling average Texas receives only 5.4% ($215 million) of National Cancer Institute (NCI) research awards.

CPRIT's $220 million annual investment in cancer research at institutions of higher education throughout the state is demonstrably making the state a national leader in cancer research and making Texas more competitive for NCI research dollars. Before CPRIT, Texas had one NCI-Designated Comprehensive Cancer Center—The University of Texas MD Anderson Cancer Center in Houston. Now there are three. The University of Texas Southwestern Medical Center in Dallas and Baylor College of Medicine in Houston have joined MD Anderson in this prestigious group. In addition, CPRIT grants have helped The University of Texas Health Science Center at San Antonio, an NCI Designated Cancer Center, solidify its position and prepare to regain comprehensive status.

These designations are important because NCI centers anchor the national cancer research effort. Currently 70 such centers in 36 states and the District of Columbia form the backbone of NCI's programs for studying and controlling cancer. By conferring the "Designated Cancer Center" status, NCI recognizes an institution for its scientific leadership, resources, and depth and breadth of its research in basic, clinical, and/or population science.

NCI-Designated Comprehensive Cancer Centers demonstrate an additional depth and breadth of research, as well as substantial transdisciplinary research that bridges these scientific areas. At any given time, hundreds of research studies are underway at the cancer centers, ranging from basic laboratory research to clinical assessments of new treatments. Many of these studies are

collaborative and may involve several cancer centers, as well as other partners in industry and the community.

The NCI grant funding to the cancer centers supports shared research resources, provides developmental support to advance scientific goals, and fosters cancer programs that draw investigators from different disciplines together. In addition, cancer center investigators are demonstrably more successful in the competition for research funding from NCI and other funding agencies and organizations. Research proposals from cancer center investigators account for about three-quarters of the successful investigator-initiated grants awarded by NCI. The centers also offer training for scientists, physicians, surgeons, and other professionals seeking specialized training or board certification in cancer-related disciplines.

As more Texas institutions achieve NCI center status, Texans benefit through greater access to clinical trials and receive advanced levels of cancer treatment not available through other health care providers. The enhanced standing of Texas' cancer centers also contributes to the state's medical education and research efforts, resulting in higher quality and greater levels of knowledge and specialization. All these activities elevate the state's reputation in medical care and advanced research. CPRIT's significant and sustained grant funding to The University of Texas Southwestern Medical Center and Baylor College of Medicine was a major factor assisting these institutions attain their comprehensive center designations. More Texas institutions are poised to gain NCI recognition with continued grant support from CPRIT.

Venture Capital Funding in Texas

Venture capitalists invest about $500 million in Texas-based life sciences companies, including those working on cancer treatments and tools. CPRIT typically invests more than $50 million each year in translational and clinical cancer research at Texas-based companies, increasing overall available life science funding in Texas by 11%.

Through August 2018, CPRIT's $380.4 million in announced company awards have resulted in an additional $1.61 billion in funding raised from life science venture capital, public offerings, and pharmaceutical companies. Without CPRIT, it is likely that this private sector follow-on investment would have gone to the East or West Coasts, where the life science industry has

historically flourished. CPRIT has also played a substantial role in launching early stage companies. To date, 12 of the 30 CPRIT companies have become publicly traded after CPRIT invested. Both the additional funding raised and the number of companies going public validate the quality of CPRIT's review process and investment strategy.

CPRIT's Economic Impact for Texas

CPRIT continues to play a vital role as the state's primary, stable source of cancer research and prevention funding.

CPRIT's efforts also enhance Texans' prosperity by reducing the economic costs of cancer. Including initial outlays and secondary effects, every $1 that CPRIT invests in screening programs results in $25.75 savings in treatment costs, preserved productivity, and other economic benefits through earlier detection of cancers. An independent economist estimates that every $1 spent on screening/prevention saves $1.94 in direct health spending.

Overall Impact of CPRIT's Activities and Investments

The creation of high-quality new jobs for Texas is a part of CPRIT's statutory mission. Through the end of fiscal year 2018, according to The Perryman Group's report, the overall impact of CPRIT's activities and investments is:

- $12.4 billion in Texas business activity;
- 110,265 jobs created through direct and indirect economic activity; and
- $551.2 million in state tax receipts and $249.8 million in local government tax receipts.

The Perryman Group also considered the alternative use of funds from another perspective. If the state did not extend CPRIT's programs and instead put the CPRIT funding to use in a non-cancer endeavor for another ten years, Texas will see a net cumulative economic loss of $141.7 billion in lost gross product and 1,207,479 of lost person years of employment. The Perryman Group estimates fiscal losses to Texas state tax receipts at $6.6 billion, and local governments at $3 billion.

CPRIT's Statutory Authority and Governing Body

CONSTITUTIONAL AND STATUTORY AUTHORITY

Created by the Texas Legislature and approved by Texas voters in 2007, CPRIT began awarding grants in 2009 to Texas-based organizations and institutions for cancer-related academic research and product development research, and for the delivery of cancer prevention programs and services.

The Texas Constitution, Article III, Section 67 authorizes the state to issue up to $3 billion for CPRIT cancer research and prevention grants and to fund CPRIT operations. The state may issue no more than $300 million in bonds per year and CPRIT may not award more than $300 million in grants annually. Based on current projections, CPRIT expects to exhaust bond funds available for grants by August 31, 2021, and for all operations by August 31, 2023.

CPRIT's governing statute, Texas Health & Safety Code Chapter 102, guides all aspects of the agency's operations.

CPRIT's statute directs the agency to:

- Create and expedite innovation in cancer research, and enhance the potential for a medical or scientific breakthrough in the prevention of cancer and cures for cancer;
- Attract, create, or expand research capabilities of public or private institutions of higher education and other public or private entities that will promote a substantial increase in cancer research and in the creation of high-quality new jobs in this state; and
- Develop and implement the Texas Cancer Plan.

CPRIT OVERSIGHT COMMITTEE

The CPRIT Oversight Committee is the Institute's governing body. The Oversight Committee approves grant awards and may adopt such policies and practices, consistent with applicable law, as it deems necessary for the conduct of its meetings and management of the agency. The Oversight Committee convenes in a public meeting at least once every quarter. In fiscal year 2018, the Oversight Committee met November 29, 2017, January 17, 2018, February 21, 2018,

May 16, 2018, and August 24, 2018. The Oversight Committee meeting agendas, meeting packets, minutes, and videos are available on CPRIT's website.

Oversight Committee Members

The Governor, the Lieutenant Governor, and the Speaker of the House each appoint three private citizens to serve as Oversight Committee members for six-year terms. At least one member appointed by each of the officers must be a physician or scientist with extensive experience in the field of oncology or public health. Pursuant to the Oversight Committee's bylaws, the committee elects a presiding officer, assistant presiding officer, and secretary in every odd-numbered year.

Oversight Committee Members

as of August 31, 2018

Appointed by the Governor **Angelos Angelou** **Austin** Term: 9/26/13 – 1/31/19	**David A. Cummings, M.D.** **San Angelo** Term: 8/27/18- 1/31/23	**Donald "Dee" Margo, II** ***Assistant Presiding Officer*** **El Paso** Term: 5/20/15 – 1/31/21
Appointed by the Speaker **Will Montgomery** ***Presiding Officer*** **Dallas** Term: 11/20/13 – 1/31/23 (Reappointed 2/10/17)	**Mahendra C. Patel, M.D.** ***Committee Secretary*** **San Antonio** Term: 9/15/17 – 1/31/21	**William Rice, M.D.** **Austin** Term: 11/14/17 – 1/31/19
Appointed by the Lt. Governor **Craig Rosenfeld, M.D.** **Dallas** Term: 9/26/13 – 1/31/17	**Vacant**	**Vacant**

Oversight Committee Program Priorities

CPRIT OVERSIGHT COMMITTEE PROGRAM PRIORITIES

Creating and expediting innovation in cancer research and enhancing the potential for medical or scientific breakthroughs in the prevention of cancer and cures for cancer requires comprehensive planning for current operations as well as longer-term goals. The Texas Legislature charged the Oversight Committee with establishing priorities on an annual basis for each of the Institute's three award programs. The priority-setting process provides transparency for how the Oversight Committee orients the Institute's funding portfolio between and within its three programs. The program priorities guide the development and issuance of program-specific Requests for Applications (RFAs) and the review of submitted applications for grant awards.

The Oversight Committee annually reviews and adjusts the priorities as circumstances change and the latest information becomes known concerning cancer-related advances in prevention, academic research, and product development research. The Oversight Committee adopted its *Program Priorities 2018* at its November 29, 2017, meeting. Each program describes individual fiscal year 2018 priorities as well as the implementation of the program priorities in this report.

At its January 17, 2018, public meeting the Oversight Committee voted to move up the deadline for considering the program priorities for the coming fiscal year. Changing the timeline provides CPRIT staff more lead time to prepare and release RFAs that incorporate the most recent priorities. The change instituted by the Oversight Committee, effective for the fiscal year 2019 program priorities, allows its priorities to guide the RFA process.

CPRIT also developed, monitored, and evaluated additional performance measures in fiscal year 2018 to document success at meeting strategic objectives, including developing cures and treatments and preventing cancer when programmatically appropriate. CPRIT staff reports at each quarterly meeting on 45 accountability, mission, and transparency metrics. In addition to fiscal accountability reviews by CPRIT's Compliance Program, non-Texas professionals with substantive experience in their appropriate fields objectively evaluate grantee progress reports.

These annual reviews of every project verify that the grantees are carrying out the qualitative work specified in the grant contract and are performing as intended.

In the section that follows, this report expands upon two of the Oversight Committee's fiscal year 2018 program priorities, "Addressing Cancer Disparities and Cancers of Importance in Texas" and "Childhood and Adolescent Cancer," to demonstrate the effect of identifying and implementing CPRIT's priorities.

Oversight Committee Program Priority: ***Addressing Cancer Disparities and Cancers of Importance in Texas***

Cancer is an equal opportunity disease; it does not discriminate. However, those that fall within a certain demographic, geographic area, or genetic profile may have unequal cancer experiences and likelihood of survival. CPRIT's Oversight Committee has made addressing cancer disparities and cancers of importance in Texas a program priority for both CPRIT's Prevention Program and its Academic Research Program. CPRIT funds prevention projects targeting the historically underserved and emphasizes cancer research efforts affecting minority populations.

The reasons for health disparities are complex and inter-related. Those at lower socio-economic levels, regardless of racial/ethnic background, are less likely to have recommended cancer screening tests and thus more likely to have cancer diagnosed at more advanced stages. Many cannot afford to live or work in safe and healthy conditions and experience higher rates of exposure to environmental risk factors. Socioeconomic status also influences access to quality health care and affordable insurance. Along with socioeconomic factors, behavioral factors such as greater tobacco use or physical inactivity contribute to the inequality in cancer incidence and outcomes.

Texas geography also presents challenges. The state designates 177 of its 254 counties as rural and more than 90% of Texas counties are medically underserved. Cancer incidence rates are higher in metropolitan areas; however, those living in rural areas are less likely to have access to care and health care professionals, less likely to receive cancer screenings than their counterparts in urban and suburban areas, and more likely to die from cancer.

CPRIT grantees use an array of innovative strategies to reach the underserved in geographically isolated areas. These include establishing partnerships and coalitions of service providers, increasing staff support, using mobile clinics, tele-mentoring, and telemedicine technologies. Disparities in incidence and survival rates also persist between border and non-border counties.

Biological differences appear to play a role in cancer disparities. Advances in genomics and other technologies improve our understanding of how biological differences may contribute to

health disparities and how biological factors interact with other factors, such as diet and the environment.

Reflecting the Oversight Committee's commitment to prioritizing cancer disparities, CPRIT's academic research Requests for Applications (RFAs) have driven interest in research focused on population disparities and three cancers of high importance in Texas: lung cancer, liver (hepatocellular) cancer (HCC), and cervical cancer. CPRIT has invested in 72 research projects since fiscal year 2015 - 16% of all CPRIT academic research awards - targeting these cancers of significance and addressing the population disparities.

Focusing on Cancers of Significance in Texas – Liver Cancer

Texas has the highest incidence rate of liver cancer among all states. Texans of Hispanic ethnicity living along the US-Mexico border have more than twice the incidence rate of HCC than non-Hispanic whites. Over the past two decades, liver cancer mortality rates have tripled. In 2018, it is estimated that more than 3,700 Texans will be diagnosed with liver and intrahepatic bile duct cancer; 2,500 will die as a result.

Researchers attribute liver cancer to a clustering of risk factors that cause liver fibrosis and cirrhosis that are the precursors of HCC, including Hepatitis C virus (HCV), nonalcoholic fatty liver disease, alcohol-related cirrhosis, and environmental aflatoxins.

Liver cancer is becoming the fastest rising cause of cancer-related deaths in the country, and **Texas has the highest death rate from liver cancer of any state**. Many Texans, including a disproportionate number of Hispanics and African Americans, have Hepatitis C, Hepatitis B, or alcoholic liver disease, which are known risk factors for liver cancer.

Since 2010, CPRIT has awarded $46 million in academic research and prevention grants addressing HCC. CPRIT invests in research projects at Texas institutions exploring the causes and developing treatments for HCC. Ten CPRIT grants totaling more than $13 million provide HCV screening and Hepatitis B vaccinations (HBV) in rural and urban areas across the state. These prevention projects cover large parts of the state, offering clinical services in Federally Qualified Heath Centers, hospital clinics and safety-net hospitals. Provider education is

prominent in several of the projects, teaching primary care providers about the importance of screening and HBV.

RP150587 ***The Texas Hepatocellular Carcinoma Consortium***

CPRIT awarded a statewide Multi-Investigator Research Award (MIRA) in 2015 to all four Texas NCI-designated cancer centers – Baylor College of Medicine, The University of Texas MD Anderson Cancer Center, The University of Texas Southwestern Medical Center, and The University of Texas Health Science Center at San Antonio. These institutions house the expertise to study the eradication of liver cancer in Texas and throughout the world. An outstanding group of investigators with complementary expertise in molecular biology, HCC biomarkers, epidemiology, and biostatistics work together on this ambitious project, called the Texas Hepatocellular Carcinoma Consortium, to develop an ecosystem of collaborative research institutions and form the epicenter for liver cancer research.

RP180674 ***Predictive Biomarkers and Novel Therapies for High-Risk Pediatric Liver Cancers***

Hepatoblastoma and hepatocellular carcinoma are the two most frequently diagnosed liver cancers in children. Patients with high risk hepatoblastoma or hepatocellular carcinoma have a dismal prognosis of 30-50% at five years post diagnosis. The Multi-Investigator Research Award project, led by Dr. Dolores Lopez-Terrada at Baylor College of Medicine, identifies and validates liver cancer molecules to improve diagnosis and chemotherapy therapy, test new drugs targeting liver cancer molecules and signaling pathways, and develop novel immunotherapy strategies. The grantees expect the project results will affect how oncologists treat children with liver cancer and that the findings will be applicable to other pediatric and adult cancers.

Liver Cancer Collaborative Action Program

In August 2018, CPRIT announced a new statewide initiative aimed at reversing the rising rates of liver cancer. CPRIT will invest up to $18 million to establish the state's first "Collaborative Action Program for Liver Cancer" (CAP). A cornerstone of the program will be the CPRIT-funded Collaborative Action Center that promotes and enables data sharing among Texas liver cancer researchers, encourages best practices for HCC prevention and early detection, and

challenges content experts, health providers, and policy makers to develop transformative initiatives to prevent liver cancer. The initiative will also support up to six investigator-initiated awards to research the increased incidence, disparities, and risk factors of HCC and to develop better early detection strategies. CPRIT's peer review panel of preeminent cancer researchers and clinicians will review and recommend the CAP applications for approval by CPRIT's Oversight Committee. CPRIT plans to announce the CAP awards in August 2019.

PP150079 and PP180063 ***STOP HCC/HCV***

Dr. Barbara Turner of The University of Texas Health Science Center at San Antonio created the *STOP HCC/HCV* program with a CPRIT Prevention Program grant awarded in May 2015. Standing for **S**creen, **T**reat, **o**r **P**revent (STOP), the program offers education about the epidemic of HCV and HCC, implements preventive screening with a focus on baby boomers, and provides management for patients who are chronically infected. The project also emphasizes community collaboration, practice transformation, and policy advocacy. Based on the success of Dr. Turner's work, CPRIT awarded a second grant in November 2017 to expand her project.

In partnership with The University of Texas Southwestern Medical Center, STOP HCC/HCV operates in primary care settings across South Texas and the Dallas area, building strong systems at each site for maintaining preventive HCV screening and delivering high-quality care for the chronically infected. The program provides physicians and staff with in-depth training and education about HCV and HCC, emphasizing the importance of early detection and explaining pathways to effective treatment for insured and uninsured patients. Since 2015, the program has worked through five primary care systems in South Texas and Parkland Hospital in Dallas where it has screened over 23,000 patients.

PP180082 ***West Texas HCV Screening and Linkage to Care***

Liver cancer is an emerging public health crisis, with El Paso having some of the highest rates of liver cancer in the nation. According to the City of El Paso's Department of Public Health Notifiable Disease Records, individuals reported more than 4,600 HCV chronic cases in El Paso County between 2010 and 2016.

In August 2018, CPRIT awarded Centro San Vicente in El Paso $1.3 million to provide HCV screening services and regional education and training about liver cancer. The program will have a significant impact in rural communities because it will integrate routine hepatitis screening services into a clinical setting.

The West Texas HCV Screening and Linkage to Care program encompasses the six-county area of Health Service Region 10 which has the highest HCC age-adjusted mortality rates in Texas, with many rural areas lacking basic access to screening services. It aims to increase access to HCV treatment and survivorship services and reduce HCC mortality rates resulting from undiagnosed or late diagnosed HCV and HBV infections among residents living in the El Paso County communities of Socorro, San Elizario, and Fabens, as well as Culberson, Presidio, and Brewster Counties.

Oversight Committee Program Priority: *Childhood Cancers*

More children die of cancer in the United States than of any other disease. Despite advances in treating childhood cancer, there is a long way to go before the cure rates and the long-term consequences of therapy are acceptable. The CPRIT Oversight Committee initially established childhood cancers as a priority area for investment in 2014, when it approved its first targeted Childhood Cancer individual investigator awards. It remains CPRIT's goal to support innovative research projects that will advance knowledge of the causes, prevention, and treatment of cancer in children and adolescents.

To date, CPRIT has awarded 139 grants totaling $251 million for grant projects researching cancer in children and adolescents. In fiscal year 2018, CPRIT granted $48 million (20% of the total Academic Research Program funds) for childhood cancer research projects. The number of CPRIT research grants devoted to childhood and adolescent cancers increased from four percent of CPRIT's academic research portfolio in 2014 to 24% in 2017. This success reflects not only the Oversight Committee's prioritization of this significant issue, but also the outstanding quality of the applications submitted to CPRIT for pediatric cancer research. The long-term effect of the awards funded by CPRIT is particularly significant since the life-years for survivors of childhood cancer far exceed that of their adult counterparts.

Nationally, the overall cure rate for all childhood cancers is approaching 70% and the five-year, event-free survival rate is almost 80%. Although current cancer treatments may be effective for some cancers, the treatments often cause significant and long-term side effects. Most childhood cancer survivors experience severe or life-threatening effects related to their cancer treatments as they age.

CPRIT is investing in research initiatives focused on pediatric cancer, which range from prevention strategies to the development of targeted small molecule and cellular therapies and survivorship issues. This report describes a few of the research grants fulfilling the Oversight Committee's commitment to develop more effective childhood cancer treatments, including therapies that are less toxic.

RR160082 ***Recruitment of First-Time, Tenure Track Faculty Members*****:** ***Kenneth Chen, M.D***

With help from a CPRIT Scholar grant, The University of Texas Southwestern Medical Center successfully recruited Kenneth Chen, M.D., a clinician-scientist, as a Tenure Track Assistant Professor in the Department of Pediatrics with secondary appointments in the Simmons Comprehensive Cancer Center. Dr. Chen's primary research focuses on understanding the molecular basis of DICER1-related cancers including Wilms tumor, the most common form of childhood kidney cancer. His work has provided the scientific rationale for new treatment approaches in Wilms tumor and has clear translational potential.

RR170026 ***Recruitment of Established Investigators: Benjamin Fregly, Ph.D.***

Dr. Benjamin Fregly, a mechanical engineer whose research focuses on the biomechanical requirements of pelvic prostheses to restore walking function, joined Rice University in 2017 through a CPRIT Established Investigator Recruitment Award. He is working with collaborators in the Texas Medical Center to develop a center dedicated to preserving the walking function of patients undergoing surgery for osteogenic sarcomas – a cancer that disproportionately affects children and young adults.

Few cancer surgeries today are as invasive or life changing as those involving the pelvis, the ring-shaped bone that anchors both the spine and hips. For pelvic cancer patients, options include removal of the cancerous bone with no reconstructive surgery; reconstruction using a combination of cadaver bone and metal implants; or a custom-designed prosthesis. Removing key parts of the pelvis can keep patients off their feet for more than a year. Outcomes are so variable that patients often go into the operating room without a clear idea of what their walking ability will be after surgery.

Dr. Fregly's goal is to maximize each patient's ability to walk after surgery. He has more than 30 years' experience building computer models to predict how well a patient will function after surgery or rehabilitation. Using motion-capture technology like that used by the film industry, Dr. Fregly and his colleagues build personalized computer models of patients. Each potential

treatment has benefits and drawbacks; these models can simulate post-treatment function for a range of treatment options considered by the physician.

Dr. Fregly's research helps not only in the design of an appropriate prosthesis, but also in guiding the surgeon in how best to preserve function when removing the cancer. Working at Rice University allows Dr. Fregly to collaborate closely with surgeons at The University of Texas MD Anderson Cancer Center, Rice University mechanical engineers who provide expertise in the design and 3D printing of custom prostheses, and orthopedic researchers at The University of Texas Health Science Center at Houston who conduct human movement testing for each patient.

RP170510 ***Telomere Maintenance Mechanisms in Neuroblastoma***

Neuroblastoma is a childhood cancer that can spontaneously regress without therapy or relentlessly progress despite intensive chemotherapy. The remarkable behavioral differences observed in neuroblastomas make it difficult for doctors to determine which tumors will require aggressive treatment. Dr. C. Patrick Reynolds' project at Texas Tech University Health Sciences Center will enable a new classification of neuroblastomas into risk groups to determine the appropriate therapy and the intensity of the treatments.

With support from a CPRIT Individual Investigator Research Awards for Cancer in Children and Adolescents, Dr. Reynolds is researching biomarkers to better identify and classify those neuroblastomas requiring treatment and to develop novel therapeutic targets for those tumors resistant to chemotherapy. He uses telomerase as a candidate biomarker based on its role in maintaining the ends of chromosomes, called telomeres, that would otherwise erode, which can lead to cell death. Telomerase maintains tumor cell telomeres by adding DNA to the ends of chromosomes. These studies leverage a collaboration with the nationwide Children's Oncology Group to access a large inventory of neuroblastoma tissues with known clinical outcomes.

RP120685 ***Molecularly Targeted Therapy for Soft Tissue Sarcoma in Texas***

This Multi-Investigator Research Award project led by Dr. Stephen Skapek at The University of Texas Southwestern Medical Center uses genomics and bioinformatics tools to explore the biology of two types of sarcoma that strike children and young adults, soft tissue sarcoma (STS)

and the Ewing sarcoma family of tumors (ESTF), and to translate this knowledge into clinical practice across the state. The projects employ sophisticated computation tools and laboratory models to sift through the genetic abnormalities that drive sarcoma growth. The effort brings together a multidisciplinary team of physicians and scientists at four Texas institutions.

Patients desperately need new therapies because less than 20% of disseminated STS or ESTF patients will survive five years after diagnosis. This survival rate has not improved in many years, despite the use of aggressive treatments incorporating surgery, radiation, and chemotherapy. Even when successful, these treatment options are associated with life-threatening or life-changing side effects.

The immediate goal is to revolutionize the care of children and young adults with STS or ESTF, improving their survival by giving therapy personalized to meet their needs. This collaborative effort creates the capacity to detect the key genetic changes – called actionable mutations – in childhood soft tissue sarcomas in real time. Treating physicians will use the information to choose the molecularly targeted drugs most likely to work in an individual sarcoma patient.

The CPRIT award supports a team of clinicians and scientists and multi-faceted core resources at The University of Texas Southwestern Medical Center, Baylor College of Medicine, The University of Texas Health Science Center at San Antonio, and Texas Children's Hospital. The team includes medical and pediatric oncologists, clinical researchers and laboratory-based scientists, anatomic and molecular pathologists, and genomics and bioinformatics experts. Key resources include the state-wide sarcoma sample collection in conjunction with molecular diagnostics studies (which will be of immediate help to sarcoma patients), and the bioinformatics and computation expertise needed to integrate the discovery work and functional validation studies into clinically meaningful information. Research conducted in this project will improve the lives of Texans with sarcoma from the initial phases of the project, culminating in practice-changing clinical trials.

RP160716 ***Texas Pediatric Patient Derived Xenograft Facility***

Dr. Peter Houghton at The University of Texas Health Science Center at San Antonio leads the Texas Pediatric Patient-Derived Xenograft (PDX) tumor repository. The CPRIT core facilities

project addresses basic oncology research questions using models of childhood cancers that more closely resemble human cancer. The PDX tumor models transplant fresh human tumor specimens from cancer patients directly into mice, creating a model that is much closer to human cancer than traditional xenograft models. These models are valuable for identifying novel therapeutics. Some of the drugs and drug combinations first tested in PDX models have now become standard of care.

Despite this progress, current models do not fully represent the genetic diversity existing in the spectrum of childhood cancers. Scientists have derived only a few models from tumors in Hispanic children even though this group of children is more likely to have poorer outcomes. With CPRIT support, this core facility established a coordinated effort to develop and characterize new PDX models primarily from Hispanic and underserved children in Texas.

Scientists generate the new PDX models using state-of-art molecular approaches and make them available to pediatric cancer researchers in Texas and around the world. The PDX models have already been important in furthering the understanding of the biology and therapy of childhood cancers. These new PDX models, representing a renewable resource, improve our coverage of the genetic diversity of childhood cancer and provide urgently needed materials that will enhance childhood cancer research.

RP180785 ***Children's Access to Regenerative Medicine in Texas (CARMIT)***

The Children's Access to Regenerative Medicine in Texas (CARMIT) core facility, led by Dr. Adrian Gee at Baylor College of Medicine, focuses on the manufacturing of innovative cell therapeutics for pediatric patients. Located at the Texas Children's Hospital, the CARMIT core facility serves researchers from Baylor College of Medicine, The University of Texas MD Anderson Cancer Center, Children's Hospital of San Antonio, and The University of Texas Southwestern Medical Center. CARMIT focuses on manufacturing innovative cell therapeutics for pediatric patients. By accelerating the movement of new findings into clinical trials,

CARMIT puts Texas pediatric researchers at a competitive advantage for national peer-reviewed and biopharmaceutical funding.

RP180819 ***Pediatric Solid Tumors Comprehensive Data Resource Core***

The *Pediatric Solid Tumors Comprehensive Data Resource Core,* led by Dr. Richard Gorlick at The University of Texas MD Anderson Cancer Center, provides a bio-repository of clinically and molecularly annotated pediatric solid tumor samples and liquid biopsies from pediatric patients. The samples span the time from initial diagnoses through treatments and either survival, recurrence, or metastasis. The University of Texas MD Anderson Cancer Center, The University of Texas Health Science Center San Antonio, and Memorial Herman Hospital-Houston are working together on this core facility project. The biospecimens are available to pediatric cancer researchers in Texas on a cost-recovery basis to facilitate studies of recurrence, second malignancies, and factors affecting quality of life following cure.

132 Childhood & adolescent cancer projects supported by CPRIT

CPRIT investment has made Texas a national leader with 12 percent, which is three times the national rate, of CPRIT's research portfolio going to childhood cancer research.

Benjamin J. Fregly, Ph.D.

Recruitment to Rice University from the University of Florida. Building on more than 30 years' experience using computer models to predict how well a patient will function after surgery or rehabilitation, Dr. Fregly's research may soon help pelvic cancer patients and their doctors choose a treatment most likely to best maintain their ability to walk after surgery.

C. Patrick Reynolds, M.D., Ph.D.

Texas Tech University Health Sciences Center

Telomere Maintenance Mechanisms in Neuroblastoma

Neuroblastoma is a childhood cancer that can spontaneously regress without therapy or relentlessly progress despite intensive chemotherapy. The remarkable behavioral differences observed in neuroblastomas makes it difficult to decide which tumors will require aggressive treatment. Dr. Reynolds' project will enable a new classification of neuroblastomas into risk groups that will then be used to determine which children should be treated and the intensity of therapy.

Stephen Skapek, M.D.

The University of Texas Southwestern Medical Center, Baylor College of Medicine, The University of Texas Health Science Center at San Antonio, and Texas Children's Hospital

Molecularly Targeted Therapy for Soft Tissue Sarcoma in Texas

This multi-investigator research award uses genomics and bioinformatics tools to explore the biology of two types of sarcoma that commonly strike children and young adults, soft tissue sarcoma (STS) and the Ewing sarcoma family of tumors (ESTF), and to translate this knowledge into clinical practice across the state. The effort brings together a multidisciplinary team of physicians and scientists at four Texas institutions.

Marina Konopleva, Ph.D.

The University of Texas MD Anderson Cancer Center

Defining and Treating Targetable Lesions in AYA Acute Lymphoblastic Leukemia

Acute lymphoblastic leukemia (ALL) is the most common form of cancer in children. Despite tremendous improvements in the outcomes, a subset of children relapses and often succumbs to their disease. In adults, the outcomes remain vastly inferior, and most patients are expected to die either of their disease or of treatment-related toxicities. The need for novel therapies is thus unquestioned. This grant looks to design and validate a genetic platform that can rapidly identify and treat high-risk patients.

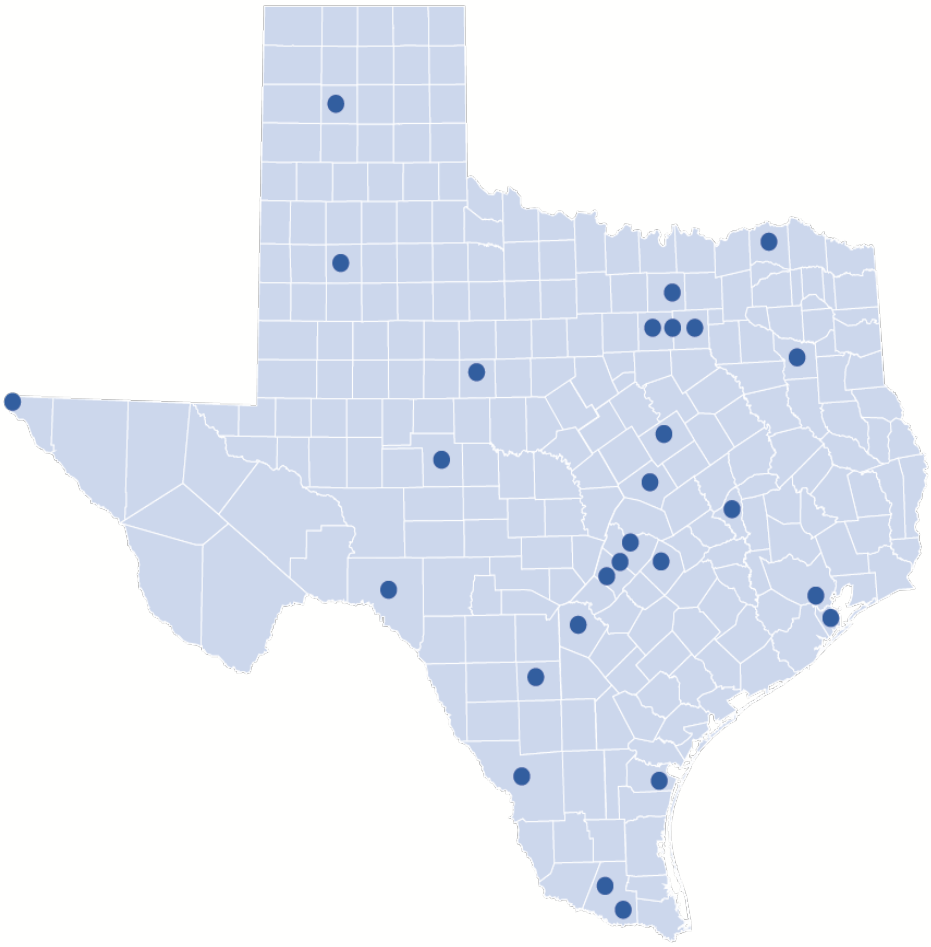
Last Updated: August 31, 2018

Cancer Prevention & Research Institute of Texas

CPRIT Grant Programs

CPRIT Investments in Academic Research, Product Development Research and Prevention Total $2.15 Billion

AWARDS TO 101 ORGANIZATIONS IN 27 CITIES



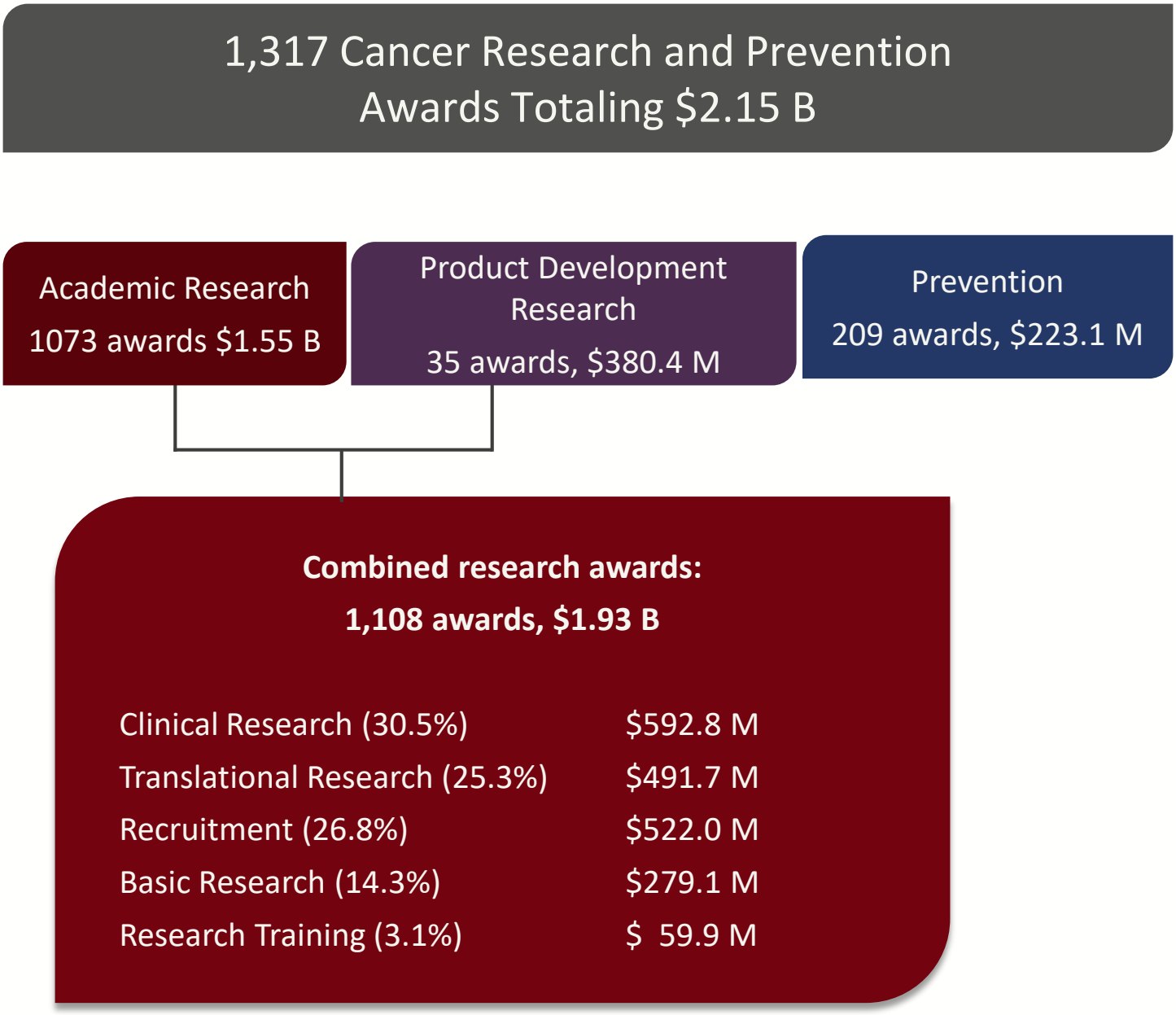
35
Academic Research Institutions

36
Community and other Organizations

30
Companies

CPRIT investments have built a vibrant life sciences and prevention infrastructure in Texas

CPRIT Investments in Academic Research, Product Development Research, and Prevention



CPRIT Grant Recipients
Fiscal Year 2018

- Baylor College of Medicine
- Baylor University
- Centro San Vicente
- CerRx, Inc.
- Formation Biologics Corporation
- Magnolia Tejas (formerly Korysso Therapeutics)
- Rice University
- Texas A&M Engineering Experiment Station
- Texas A&M University
- Texas A&M University System Health Science Center
- Texas Southern University
- Texas Tech University
- Texas Tech University Health Sciences Center
- Texas Tech University Health Sciences Center at El Paso
- The Methodist Hospital Research Institute
- The University of Texas at Austin
- The University of Texas at Dallas
- The University of Texas Health Science Center at Houston
- The University of Texas Health Science Center at San Antonio
- The University of Texas MD Anderson Cancer Center
- The University of Texas Medical Branch at Galveston
- The University of Texas Southwestern Medical Center
- University of Houston

CPRIT GRANT PROGRAMS: ACADEMIC RESEARCH

Over the past decade Texas has emerged as a cancer research powerhouse. CPRIT investments in basic, clinical, and population research - now exceeding $1.5 billion - provide the catalyst for development of new centers of cancer research excellence based at institutions across the state and boost Texas' national and international reputation in cancer research. Most importantly, CPRIT research investments have led to new life-saving treatments and prevention strategies that save the lives of Texans.

In 2018, CPRIT's Academic Research Program awarded 107 grants totaling $197.6 million. Since 2009, CPRIT has funded 1,073 academic research projects totaling $1.55 billion at 36 institutions and organizations across the state. The academic research grant projects funded by CPRIT are part of an iterative cycle with observations emerging from the laboratory making their way to the patient's bedside and back again to the laboratory. Essential players in this cycle are basic scientists, physician-scientists, and clinical and population researchers at the state's research institutions.

CPRIT supports the most creative ideas and meritorious projects brought forward by the cancer research community in Texas. The overarching principles for awarding CPRIT funds are scientific excellence and impact on reducing the burden of cancer, both of which are critically important to enhance the life sciences infrastructure in Texas. This enables CPRIT's effect on cancer research to extend for years beyond the lifetime of the program.

The goals of CPRIT's Academic Research Program are to:

- Discover new insights about cancer that can lead to prevention, early detection, and more effective treatments;
- Translate discoveries into practical advances in cancer diagnosis, treatment, and survivorship; and
- Increase the prominence and stature of Texas in the fight against cancer.

Academic Research Program Priorities

In addition to the investments in recruitment, training, and core facilities, CPRIT's Academic Research Program is committed to funding projects in critical but underfunded areas of cancer research. Opportunities for the strategic deployment of funds include cancer prevention and early detection research, computational biology and analytic methods, childhood cancers, and cancers of importance in Texas with a special emphasis on hepatocellular cancer because of the dramatic rise in its incidence in Texas over the past five years.

The fiscal year 2018 priorities adopted by the Oversight Committee for the Academic Research Program include funding projects that address:

- Recruitment of outstanding cancer researchers to Texas;
- Investment in core facilities;
- A broad range of innovative, investigator-initiated academic research projects;
- Prevention and early detection;
- Computational biology and analytic methods;
- Childhood cancers; and
- Population disparities and cancers of importance in Texas (lung, liver, cervix cancers).

Table 1 reflects the number of awards and total funding for each of the Oversight Committee's Academic Research Program priorities in fiscal year 2018.

TABLE 1: FY 2018 DATA BY ACADEMIC RESEARCH PROGRAM PRIORITIES

Priorities Addressed	Number of Grants*	Award Amount
Recruitment of outstanding cancer researchers to Texas	23	$71,940,000
Investment in core facilities	10	$45,220,000
A broad range of innovative, investigator-initiated academic research projects	75	$82,035,933
Prevention and early detection	5	$7,496,479

Priorities Addressed	Number of Grants*	Award Amount
Computational biology and analytic methods	6	$20,762,956
Childhood cancers	19	$39,307,357
Population disparities and cancers of importance in Texas (lung, liver, cervix cancers)	10	$14,516,337

**Some grants address more than one priority*

Review Process and Grant Mechanisms

CPRIT academic research award applications undergo rigorous scientific reviews conducted by seven independent peer review panels. The peer review panels are composed of prominent cancer researchers that live and work outside of Texas, selected for their distinguished expertise.

CPRIT directs these experts to assess the research proposals based on scientific merit and potential impact on cancer. Eminent cancer researchers chair each of the seven panels. Together these seven chairs make up the Scientific Review Council, led by Richard Kolodner, Ph.D., a member of the National Academy of Sciences and Distinguished Professor in the departments of Medicine and Cellular and Molecular Medicine at the University of California, San Diego School of Medicine, and head of The Ludwig Institute for Cancer Research in San Diego.

CPRIT utilizes a variety of grant award mechanisms to achieve the guiding principles and goals established for the Academic Research Program. During fiscal year 2018, CPRIT released the following Requests for Applications (RFAs):

- *Recruitment Awards* build a critical mass of cancer researchers in Texas by supporting the recruitment of premier cancer researchers at all levels to academic institutions in Texas.
- *Core Facilities Support Awards* facilitate the development or improvement of core facilities that provide valuable services to support and enhance scientifically meritorious cancer research projects.

- *Individual Investigator Research Awards (IIRAs)* support acquisition of new fundamental knowledge about cancer and cancer development as well as the development of state-of-the-art technologies and tools. Researchers may explore new methods and approaches for investigating a question of importance that the scientific community has not addressed adequately or for which there may be an absence of an established paradigm or technical framework. CPRIT also released targeted IIRAs soliciting novel research proposals in childhood and adolescent cancers, computational biology, cancer prevention with an emphasis on funding innovative strategies to increase implementation of evidence-based practices, and clinical translation.
- *High-Impact/High-Risk Research Awards* provide short-term funding to explore the feasibility of high-risk projects that, if successful, contribute major new insights into the etiology, diagnosis, treatment, or prevention of cancers.
- *Multi-Investigator Research Awards* stimulate collaboration among researchers and clinicians working together on a common problem in cancer.

Academic Research Portfolio in Fiscal Year 2018

CPRIT awarded $197.6 million in academic research grants in fiscal year 2018, including $71.9 million in recruitment awards bringing 23 cancer researchers to Texas research institutions (see Tables 2 and 3). A complete list of awards by grant recipient for each fiscal year and cumulatively, is available on CPRIT's website at http://grantreports.cprit.texas.gov. CPRIT also provides a searchable database of every CPRIT award at https://www.cprit.texas.gov/grants-funded

TABLE 2: FY 2018 ACADEMIC RESEARCH AWARDS DATA BY REQUEST FOR APPLICATIONS			
Funding Mechanism	Applications Received	Applications Awarded	Total Funding
Core Facility Support Awards	27	10	$45,220,000
High-Impact/High-Risk	149	25	$5,000,000
Individual Investigator Research Awards (IIRA)	347	26	$22,460,000
IIRA Cancer in Children and Adolescents	37	9	$10,100,000
IIRA for Clinical Translation	54	5	$9,460,000
IIRA Computational Biology	43	1	$900,000
IIRA Prevention and Early Detection	40	3	$2,600,000
Multi-Investigator Research Awards	23	5	$29,940,000
Total	**720**	**84**	**$125,680,000**

Recruiting preeminent researchers to Texas is crucial to developing Texas' life sciences infrastructure. In fiscal year 2018, Texas added 23 talented CPRIT Scholars to the state's stable of prestigious research scholars. Through August 31, 2018, CPRIT has recruited 159 premier cancer researchers to 18 Texas institutions, making the CPRIT Scholar recruitment program the envy of research institutions across the nation. CPRIT Scholars coming to Texas bring novel expertise as well as additional research funding, catalyzing new centers of research excellence across Texas. These researchers, together with state's homegrown talent, are creating the critical mass of science needed to attract capital for the development of products for cancer prevention, diagnosis, and treatment.

TABLE 3: FY 2018 RECRUITMENT AWARDS DATA BY REQUEST FOR APPLICATIONS				
Funding Mechanism	Applications Received	Review Council Recommended	Recruitment Offers Made and Accepted	Total Funding*
Established Investigators	15	7	3 (+2 pending)	$17,986,494
Rising Stars	10	4	3	$12,000,000
First –Time Tenure Track Faculty Members	33	19	14	$28,000,000
Total	**58**	**30**	**20 (+2 pending)**	**$57,986,494**

* The total funding for FY 2018 is $69,986,494 if the two recruits accept the pending offers

Representative Academic Research Program Grants Awarded in Fiscal Year 2018

RP180381 ***Mass Spectrometry Imaging to Uncover Predictive Metabolic Markers of Ovarian Cancer Surgical Outcome and Treatment Response***

Dr. Livia Eberlin, Assistant Professor of Chemistry at The University of Texas at Austin, is developing new ways to identify cancerous tissue to improve outcomes for patients using a chemical analysis method called mass spectrometry. One tool she has developed, called the "MasSpec Pen," enables surgeons to rapidly differentiate cancerous tissue from healthy tissue directly in patients in a surgical setting, which might help them decide what to remove and what to leave intact. Clinicians can also use the MasSpec Pen on tissue samples taken from a patient to help clinicians diagnose disease and choose the most effective treatment option for an individual.

The MasSpec Pen allows controlled and automated delivery of a discrete water droplet to a tissue surface for efficient extraction of biomolecules, which the tool then delivers to the mass spectrometer for molecular analysis. Results from earlier CPRIT awards to Dr. Eberlin provide evidence that surgeons may use the MasSpec Pen as a clinical and intra-operative tool for ex-vivo and in-vivo cancer diagnosis. The research supported by this award will investigate the use of the MasSpec Pen in the management of patients undergoing surgery for ovarian cancer. In the past year the MacArthur Foundation recognized the promise of Dr. Eberlin's research with the

award of a MacArthur Fellowship, sometimes called the “Genius Award,” that provides her with a $625,000, no-strings-attached grant.

RP180473 ***Clinical trials of C188-9, an Oral Inhibitor of Signal Transducer and Activator of Transcription (STAT) 3, in Patients with Hepatocellular Carcinoma***

This award to Dr. David Tweardy, Professor of Internal Medicine at The University of Texas MD Anderson Cancer Center, will support a first-in-man clinical trial in patients with advanced hepatocellular carcinoma (HCC). Past CPRIT and NIH awards supported the early discovery of C188-9, a novel cancer drug that selectively targets an oncogene, STAT3, implicated in HCC. A CPRIT Early Translational Research Award supported the manufacturing and preclinical testing required for preclinical studies of C188-9, which found targeting STAT3 with C188-9 had significant efficacy against HCC in laboratory models with little evidence of toxicity to normal tissues. In all, CPRIT has awarded $5.8 million to support the development of the new STAT3 inhibitor from concept to this stage of first-in-man testing against HCC.

Clinical development of C188-9 will have additional support from Tvardi Therapeutics Inc., a clinical-stage Houston-based biopharmaceutical company that recently completed a $9 million Series A financing round based in part upon these discoveries by Dr. Tweardy.

RP180404 ***Noninvasive Detection of Anthracycline-Induced Cardiotoxicity Using Hyperpolarized Carbon 13-Based Magnetic Resonance Spectroscopic Imaging***

CPRIT awarded Dr. Vlad Zaha, Assistant Professor of Internal Medicine at The University of Texas Southwestern Medical Center, this grant to evaluate a novel imaging technique, hyperpolarized carbon 13 MRI, in breast cancer patients receiving the chemotherapy agent doxorubicin. Doxorubicin treatment carries a significant risk of long-term heart failure because of damage to mitochondria, the subcellular structures that generate energy for heart contraction, However, individual patient sensitivity to anthracycline-induced cardiotoxicity varies and cannot be predicted, putting many patients receiving doxorubicin at risk and emphasizing the critical need for better methods for the early detection of chemotherapy-related heart damage. The hyperpolarized carbon 13 MRI has been developed as a noninvasive way to detect at an early stage the biochemical changes associated with this chemotherapy-induced heart damage. The University of Texas Southwestern Medical Center is the first in the United States to apply this

novel methodology for heart studies in patients with potential to establish a more effective personalized profile of early detection of cardiotoxicity.

Academic Research Grant Recipient Institutions

- Baylor College of Medicine
- Baylor Research Institute
- Baylor University
- Rice University
- Texas Engineering Experiment Station
- Texas A&M Health Science Center Research Foundation
- Texas A&M University
- Texas A&M University Health Science Center Institute of Biosciences and Technology
- Texas A&M University System Health Science Center
- Texas AgriLife Research
- Texas Southern University
- Texas State University - San Marcos
- Texas Tech University
- Texas Tech University Health Sciences Center
- Texas Tech University Health Sciences Center at El Paso
- The Methodist Hospital Research Institute
- The University of Texas at Arlington
- The University of Texas at Austin
- The University of Texas at Dallas
- The University of Texas at El Paso
- The University of Texas at San Antonio
- The University of Texas Health Science Center at Tyler
- The University of Texas Health Science Center at Houston
- The University of Texas Health Science Center at San Antonio
- The University of Texas MD Anderson Cancer Center
- The University of Texas Medical Branch at Galveston
- The University of Texas Southwestern Medical Center
- The University of Texas System
- University of Houston
- University of North Texas
- University of North Texas Health Science Center at Fort Worth

CPRIT GRANT PROGRAMS: PRODUCT DEVELOPMENT RESEARCH

Groundbreaking science is most valuable when it is translated into cancer drugs, diagnostics, and therapies available to Texans. CPRIT's Product Development Research Program funds projects at Texas-based companies developing novel cancer products or services. Product development activities translate a novel laboratory finding into a safe, reliable product available to treat cancer patients. CPRIT supports projects that accelerate the development of promising research discoveries through the crucial preliminary stages of regulatory development.

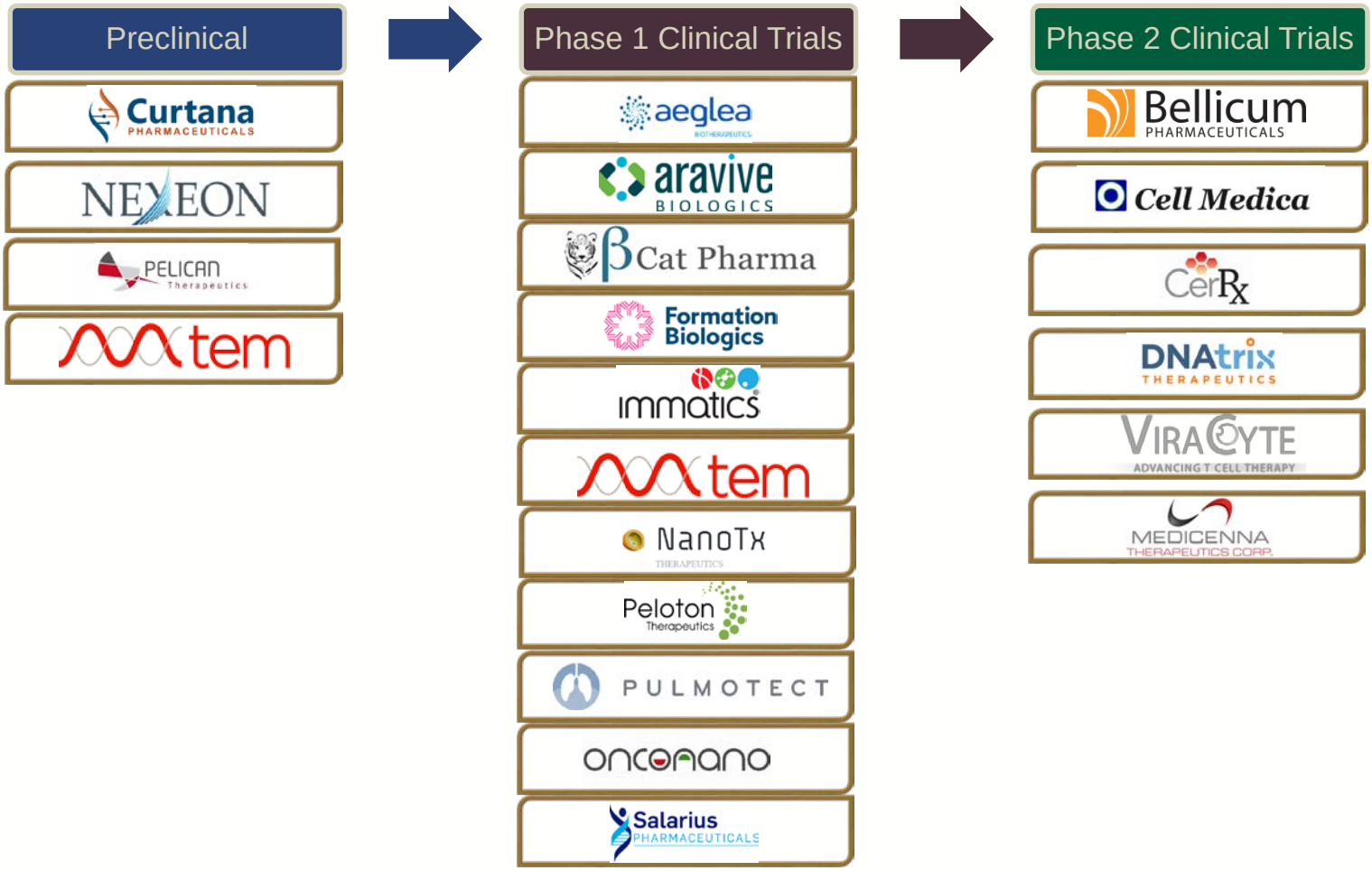
In fiscal year 2018 the CPRIT Product Development Research Program awarded three grants totaling $50.6 million. Since 2010, CPRIT has awarded 35 product development research grants totaling $380.4 million. The Product Development Research Program funds clinical research to confirm the safety and efficacy on the target patient population, as well as necessary steps to gain regulatory approval required prior to commercial use. Startup companies typically conduct these early stage preclinical and clinical activities. Developing novel cancer drugs and diagnostics is expensive, with the latest studies showing the cost of a new therapeutic can be up to $3 billion. CPRIT invests in early stage companies where private capital is hardest to obtain.

CPRIT provides only a portion of the funding required to complete development with the bulk of funding typically originating from private sources. However, CPRIT's investment is critically important because it funds development activities that are early in the process but necessary for any further progress. CPRIT's investments also increase the number of cancer therapies in development in Texas, stimulating the Texas life sciences ecosystem.

CPRIT's Product Development Research Program has committed $380.4 million to 30 Texas companies. In turn, the CPRIT companies have raised $1.61 billion in additional investments after their CPRIT awards. The companies' ability to leverage CPRIT's early investments at a rate of 4:1 strongly indicates angel and venture capital confidence in the peer review and due diligence processes for CPRIT's product development research awards.

During fiscal year 2018, 16 companies had CPRIT projects in clinical trials. Twenty-two companies with CPRIT-funded projects have connections with Texas institutions, further strengthening the life science infrastructure and ecosystem across the state.

CPRIT Companies in Active Clinical Trials



Texas Company/Academic Institution Collaborations

Product Development Research Priorities

To invest strategically, these principles CPRIT's Product Development Research Program:

- Supporting the commercial development of novel products to address unmet cancer diagnosis and treatment needs;
- Stimulating the Texas life sciences ecosystem by funding in spaces where private capital is most difficult to obtain, known as the "Valley of Death" between research and private funding;
- Investing in projects based on sound scientific research with strong management and sound business plans that will be attractive to private investment; and
- Providing an appropriate return on Texas taxpayer investment.

The number of scientifically and commercially attractive product development opportunities in Texas exceeds CPRIT's ability to fund them. CPRIT directs its resources toward maximizing clinical benefits and identifying the most promising projects. The fiscal year 2018 program priorities adopted by the Oversight Committee for the Product Development Research Program address:

- Supporting development of novel projects that offer therapeutic or diagnostics not currently available, i.e., disruptive technologies;
- Funding projects addressing large or challenging unmet medical needs;
- Investing in early stage projects when private capital is least available;
- Stimulating commercialization of technologies developed at Texas institutions;
- Supporting new company formation in Texas or attracting promising companies to Texas that will recruit staff with life sciences expertise, especially experienced C-level staff to new life science companies in Texas; and
- Providing appropriate return on Texas taxpayer investment.

Table 4 shows how the fiscal year 2018 Product Development Research Program awards fulfilled the Oversight Committee's priorities.

TABLE 4: FY 2018 FUNDING BY CPRIT PRODUCT DEVELOPMENT RESEARCH PROGRAM PRIORITIES*		
Priorities Addressed	# Grants	Award Amount
Funding novel projects that offer therapeutic or diagnostics not currently available, i.e., disruptive technologies	3	$50,587,540
Funding projects addressing large or challenging unmet medical needs	3	$50,587,540
Investing in early stage projects when private capital is least available	3	$50,587,540
Stimulating commercialization of technologies developed at Texas institutions	2	$31,737,540
Supporting new company formation in Texas or attracting promising companies to Texas that will recruit staff with life sciences expertise, especially experienced C-level staff to new life science companies in Texas	1	$19,953,624
Providing appropriate return on Texas taxpayer investment	3	$50,587,540

*Some grants address more than one priority

Review Process and Grant Mechanisms

CPRIT uses a merit-based selection process, adjudicated by subject matter expert peer reviewers, to select the most promising product development research grant applicants. The multi-stage selection process includes in-person presentations by the applicants once they have entered the final evaluation stage. Proposed projects that the review panel finds sufficiently compelling after the in-person presentations undergo due diligence review. This review involves an in-depth evaluation of the proposal's underlying intellectual property, clinical trial design, regulatory affairs, manufacturability of product, marketing, and other relevant factors. Historically, CPRIT awards grant funds to ten percent of the companies that apply.

The Product Development Research Program released two grant mechanisms in each of the two grant review cycles for fiscal year 2018.

- *Texas Company Product Development Awards* support Texas based early-stage start-up and established companies in the development of innovative products, services, and infrastructure with significant potential impact on patient care. The proposed project must further the development of new products for the diagnosis, treatment, or prevention of cancer; must establish infrastructure that is critical to the development of a robust industry; or must fill a treatment or research gap.
- *Company Relocation Product Development Awards* support companies that are willing to relocate to Texas in developing new products for the diagnosis, treatment, or prevention of cancer; establishing infrastructure that is critical to the development of a robust industry; or filling a treatment or research gap.

The Product Development Review Council (PDRC), comprised of experts in the fields of cancer research and cancer product development, monitors the status of product development research grant projects. The PDRC reviews updates and reports to ensure companies are making appropriate progress toward project milestones. CPRIT disburses grant funding to the company in tranches based upon documented progress and may terminate the funding if the company is not meeting its contractual objectives. Award contracts also include a royalty obligation payable post commercialization. CPRIT's revenue sharing terms provide appropriate return to Texas taxpayers and are structured so that the company can attract subsequent investors.

Product Development Research Award Portfolio

As of the end of fiscal year 2018, CPRIT had granted 35 awards to 30 individual companies across multiple sectors of the cancer market including development services, diagnostics, devices, and therapeutics. Two-thirds of CPRIT Product Development Research program grants (90% of invested capital) support projects at companies developing novel drug, cell, and biologic therapies for cancer patients. The novel therapeutics funded by the CPRIT Product Development Research Program are in preclinical or clinical development. The remaining program portfolio investments (10% invested capital) are in other sectors, including development services, diagnostics, and devices. Four of these companies have commercialized their service or product.

Table 5 summarizes CPRIT's portfolio of Product Development Research program projects as of August 31, 2018. A complete list of awards by grant recipient for each fiscal year and cumulatively, is available on CPRIT's website at http://grantreports.cprit.texas.gov. CPRIT also provides a searchable database of every CPRIT award at https://www.cprit.texas.gov/grants-funded.

TABLE 5: CPRIT PRODUCT DEVELOPMENT RESEARCH PORTFOLIO				
ACTIVE PRODUCT DEVELOPMENT RESEARCH GRANT PROJECTS				
Company	Sector	Cancer Indications	Project Focus	Total Award Amount
Aravive Biologics, Inc. (formerly Ruga Corp.)	Biologic Therapy	Multiple Cancers	Targeted Immunotherapy	$20,000,000
Bellicum Pharmaceuticals, Inc. (Two awards: one active, one closed)	Cell Therapeutics	Leukemia	De-activated T-cells for Leukemia	$16,946,716
Beta Cat Pharmaceuticals, LLC	Molecular Therapy	Colon	Betacatine pathway inhibitor	$15,908,085
CerRx, Inc. (Two awards: one active, one closed)	Molecular Therapy	Lymphoma	Small molecule affects tumor cell wall	$11,783,916
Curtana Pharmaceuticals, Inc.	Molecular Therapy	Glioblastoma	Targeted small molecule therapy	$7,580,185
Formation Biologics Corp. (formerly Armada Pharma) (Two awards)	Biologic Therapy	Multiple Cancers	Antibody drug conjugate	$31,600,000
Immatics US Inc.	Biologic Therapy	Multiple Cancers	Targeted Immunotherapy	$19,652,175
Magnolia Tejas Corp. (formerly Korysso Therapeutics, Inc)	Molecular Therapy	Chemotherapy-Induced Peripheral Neuropathy and Chemo Brain	Small molecule therapeutic	$19,953,624
Medicenna Therapeutics, Inc.	Molecular Therapy	Glioblastoma	Cytokines for IL4 receptor	$14,140,090

ACTIVE PRODUCT DEVELOPMENT RESEARCH GRANT PROJECTS				
Company	Sector	Cancer Indications	Project Focus	Total Award Amount
Molecular Templates, Inc. (Two awards)	Biologic Therapy	Blood Cancers	Antibody drug conjugate	$25,800,000
Nexeon MedSystems, Inc. (formerly Rosellini)	Devices	Multiple Cancers	Neuro-stimulation device	$967,000
OncoNano Medicine, Inc.	Devices	Multiple Cancers	Surgical device for margin detection	$6,000,000
Pelican Therapeutics, Inc.	Biologic Therapy	Multiple Cancers	Targeted Immunotherapy	$15,245,222
Salarius Pharmaceuticals, LLC	Molecular Therapy	Ewing's Sarcoma	LSD 1 Inhibitor	$18,668,717
ViraCyte LLC	Cell Therapeutics	Multiple Cancers	Activated T-cells	$8,998,067
COMPLETED PRODUCT DEVELOPMENT RESEARCH GRANT PROJECTS				
Company	Sector	Cancer Indications	Project Focus	Total Award Amount
Aeglea Biotherapeutics, Inc. (formerly AERase, Inc.)	Molecular Therapy	Multiple Cancers	Enzyme for amino acid depletion	$19,806,145
Apollo Endosurgery, Inc.	Devices	Multiple Cancers	Minimally invasive resection device	$5,001,063
Asuragen, Inc.	Diagnostics	Multiple Cancers	Genetic/Oncology diagnostics	$6,837,265
Bellicum Pharmaceuticals, Inc. (Two awards: one active, one closed)	Cell Therapeutics	Leukemia	De-activated T-cells for Leukemia	$5,680,310
Caliber Biotherapeutics, LLC	Biologic Therapy	Blood Cancers	Plant-Based Vaccine	$12,808,151

COMPLETED PRODUCT DEVELOPMENT RESEARCH GRANT PROJECTS				
Company	Sector	Cancer Indications	Project Focus	Total Award Amount
Cell Medica, Inc.	Cell Therapeutics	Lymphoma	Activated T-cells	$15,571,303
CerRx, Inc. (Two awards: one active, one closed)	Molecular Therapy	Lymphoma	Small molecule affects tumor cell wall	$6,000,000
DNAtrix, Inc.	Biologic Therapy	Glioblastoma	Adenovirus for glioblastoma	$10,813,623
ESSA Pharma Inc.	Molecular Therapy	Prostate	Androgen receptor blocker	$12,000,000
Fujifilm Diosynth Biotechnologies Texas, LLC (formerly Kalon)	Tools & Services	Multiple Cancers	Contract biologics manufacturing facility	$7,901,420
InGeneron, Inc.	Diagnostics	Multiple Cancers	System to isolate circulating cancer cells	$198,111
Mirna Therapeutics, Inc. (Two awards)	Biologic Therapy	Multiple Cancers	Tumor suppressor, Micro RNA	$27,062,530
NanoTX Therapeutics, Inc.	Devices	Glioblastoma	Nanoparticle radiation therapy	$2,000,000
Peloton Therapeutics, Inc.	Molecular Therapy	Renal	Transcription factor agonist	$3,201,002
Pulmotect, Inc.	Molecular Therapy	Multiple Cancers	Molecular anti-infective therapy	$7,126,398
Rules-Based Medicine, Inc.	Tools & Services	Multiple Cancers	Biomarker test development	$3,024,432
Visualase, Inc.	Devices	Prostate	MRI guided laser tumor ablation	$2,151,776
TOTAL				**$380,427,326**

Product Development Research Program Grants Awarded in Fiscal Year 2018

DP18040 ***Formation Biologics Corporation***

Formation Biologics is developing an innovative pipeline of anti-cancer biotherapeutics called antibody-drug conjugates (ADCs). Scientists have engineered these next-generation treatments to kill cancer cells while sparing healthy cells. CPRIT first invested in the development of Formation's lead ADC product, AVID100, in 2015 (at the time, the company was known as Armada Pharmaceuticals.) With the initial CPRIT investment, the company demonstrated excellent safety and efficacy of AVID100 in preclinical work and a multi-center Phase I clinical study. The trial began at South Texas Accelerated Research Therapeutics in San Antonio.

Formation will use the second CPRIT investment to expand testing of AVID100 in Phase IIa clinical trials in three cancers (breast, squamous cell carcinoma of the head and neck, and non-small cell lung cancer) with significant unmet medical need. The company plans to grow its operations in Austin, creating high-quality jobs and training staff in drug development and clinical trial operations. Cancer patients in Texas will have the potential to be among the first to benefit from treatment with AVID100.

DP180042 ***CerRx Inc.***

This is the second investment CPRIT has made in CerRx, Inc., an early stage company based in Lubbock. CerRx, Inc. is developing a new cancer drug with improved effectiveness and fewer side-effects than current treatments. CPRIT-funded clinical trials have demonstrated that CerRx's lead drug candidate, intravenous (IV) fenretinide, is particularly effective in treating T-cell lymphomas (in some cases completely eradicating the cancers), while having fewer side effects than competing therapies.

With CPRIT's investment, CerRx will initiate a second clinical trial to study IV fenretinide to treat cutaneous T-cell lymphoma (CTCL). Doctors diagnose 3,000 new cases of CTCL in the U.S. every year. CTCL treatments available now are usually initially successful but lose effectiveness as the disease progresses. One third of CTCL patients will progress to advanced

stages and one quarter will die regardless of the type of therapy administered. CerRx contends that IV fenretinide may revolutionize the way clinicians will treat CTCL.

DP180048 ***Magnolia Tejas Corp. (formerly Korysso Therapeutics, Inc.)***

Chemotherapy is frontline treatment for millions of cancer patients, but it can cause devastating side effects. Patients can manage some side effects, like nausea, with medication. But the most common serious side effect, the burning pain, tingling and loss of sensation in the patient's hands and feet, has no effective treatment. This condition, known as chemotherapy-induced peripheral neuropathy (CIPN), decreases the patient's quality of life and is the main reason patients fail to complete their treatments. Currently, there are no medicines to prevent CIPN.

Chemotherapy may also damage the brain, causing problems with memory and higher cognitive function. Chemotherapy-induced cognitive dysfunction, known as "chemo brain," presents as a troubling mental fog and may permanently disable some patients. According to estimates there will be more Americans living with chemo brain than Alzheimer's by 2024. There are no medicines to prevent or treat this condition.

Magnolia Tejas Corp. (formerly known as Korysso Therapeutics, Inc.) is a Houston-based biotechnology startup with a single mission - developing treatments that prevent these side effects and allow patients to complete their chemotherapy and become healthy survivors. Based on technology invented at MD Anderson Cancer Center, Magnolia Tejas is starting clinical trials with its first drug candidate, KOR-8287. CPRIT's investment allows Magnolia Tejas to prove that their breakthrough medicine is effective at preventing CIPN and chemo brain from developing in patients.

CPRIT GRANT PROGRAMS: PREVENTION

CPRIT's prevention grant awards make it possible for cancer prevention interventions and services to reach more Texans to save lives and reduce the burden of cancer. Because of proven prevention interventions, early detection, and better treatments, cancer mortality rates are steadily declining. Texas has seen a nine percent drop in the death rate from cancer between 2010 and 2015 (the latest data available). Over that five-year period, efforts across Texas addressing cancer incidence and mortality have potentially averted 10,700 deaths.

CPRIT's Prevention Program awarded 20 grants totaling $26.8 million in fiscal year 2018. Through August 31, 2018, CPRIT's Prevention Program has funded 209 grants totaling $223,140,705 and delivered nearly five million services to Texans. These include 2.3 million education and training services and 2.4 million clinical services. The clinical services provided by CPRIT grantees consist of screenings and diagnostic services as well as vaccinations, tobacco cessation, genetic testing and counseling, and survivor care services.

CPRIT Prevention Program's 209 grant projects have delivered:

- 227,575 prevention vaccinations;
- 226,138 tobacco cessation services;
- 135,910 genetic testing and counseling services;
- 23,039 survivor care services; and
- 1,214,979 screenings and diagnostics for breast, cervical, colorectal, lung, and HPV- related cancers as well as hepatitis screening, with 355,689 recipients who had never been screened before.

Through August 31, 2018, CPRIT's screening and diagnostic projects detected 13,277 cancer precursors and 3,364 cancers.

Approximately half of all cancers are preventable. However, the ability to meaningfully reduce cancer death rates depends, in part, on applying currently available evidence-based prevention interventions more broadly. Through its Prevention Program, CPRIT invests in evidence-based

community interventions so that innovative technologies and services are available across the state, with priority given to medically underserved areas and populations.

In addition to improving the health of people in Texas, CPRIT's prevention grants benefit the healthcare system and foster greater collaborations across the state. Health system improvements include decreasing wait times for diagnostic testing, reducing the number of people lost to follow-up, implementing patient reminder systems, enhancing electronic medical records, and training a cadre of community health care workers to help educate and navigate people through the system. CPRIT grants stimulate greater collaboration among professional colleagues, academic institutions, community organizations, and clinics.

Preventing cancers, or early detection, also provides economic benefits. According to The Perryman Group, every $1 spent through CPRIT for screening and prevention leads to $25.75 in treatment cost-savings, preserved productivity, and other economic benefits through earlier detection of cancers.

The Prevention Program prioritizes evidence-based interventions and funding interventions across the prevention continuum. CPRIT funds programs and services, for any cancer type, that are culturally appropriate for the target population and validated by documented research or applied evidence.

CPRIT funds quality Prevention Program proposals focused on:

- Primary prevention: Reducing risk or preventing cancer from occurring (e.g., vaccine-conferred immunity, tobacco cessation);
- Secondary prevention: Early detection of cancer to prevent it from spreading and treating diagnosed cases when the opportunity for greatest success exists (e.g., screening/early detection for breast, cervical, lung, and/or colorectal cancer); and
- Tertiary prevention: Reducing risk of recurrence and improving quality of life for survivors and families (e.g. physical rehabilitation/therapy, psychosocial interventions, palliative care).

Prevention Program Priorities

The Prevention Program reviews data on cancer incidence, mortality, and disparities (geographic, ethnic, etc.) annually to identify priorities and areas of emphasis. The fiscal year 2018 Prevention Program priorities adopted by the Oversight Committee include funding projects that prioritize:

- Populations disproportionately affected by cancer incidence, mortality, or cancer risk prevalence;
- Geographic areas of the state disproportionately affected by cancer incidence, mortality, or cancer risk prevalence; and
- Underserved populations.

Table 6 illustrates targeted priorities as addressed by the 20 Prevention Program grants awarded in fiscal year 2018.

TABLE 6: FY 2018 FUNDING BY PREVENTION PROGRAM PRIORITIES

Priorities Addressed	Number of Grants*	Award Amount
Populations disproportionately affected by cancer incidence, mortality, or cancer risk prevalence	15	$22,187,931
Geographic areas of the state disproportionately affected by cancer incidence, mortality, or cancer risk prevalence	14	$21,408,341
Underserved populations	20	$28,022,756

**Some grants address more than one priority*

Review Process and Grant Mechanisms

CPRIT Prevention grant applications undergo peer review by two independent peer review panels. A renowned public health expert chairs each panel. CPRIT selects peer reviewers from outside of Texas who are prominent public health experts who can assess the merit and potential impact on cancer. The Prevention Review Council, made up of the two panel chairs and a Review Council Chair, conducts a second stage of review focusing on programmatic considerations. These may include geographic distribution, cancer type, population served, and type of program or service.

The Institute released a variety of requests for applications in fiscal year 2018 to achieve the goals of the Prevention Program. These include:

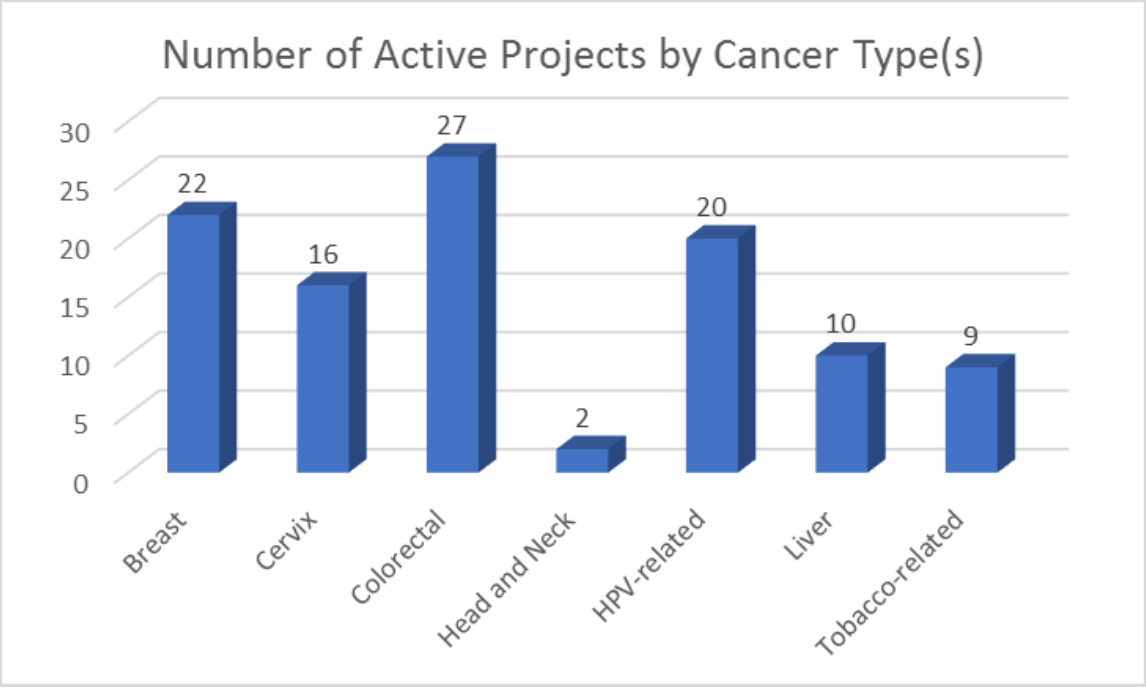
- *Tobacco Control and Lung Cancer Screening Awards* support projects that address tobacco prevention and cessation, as well as screening for early detection of lung cancer for high-risk populations. CPRIT issued this award for the first time in fiscal year 2018.
- *Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations Awards* seek projects that deliver evidence-based services to prevent cancer in underserved populations without adequate access to cancer prevention interventions and health care, bringing together networks of public health and community partners to carry out programs tailored for their communities.
- *Evidence-Based Cancer Prevention Services Awards* fund projects that provide the delivery of evidence-based prevention services (e.g., primary prevention, screening, survivorship services).
- *Dissemination of CPRIT-Funded Cancer Control Interventions Awards* support projects that facilitate the dissemination and implementation of successful CPRIT-funded, evidence-based cancer prevention and control interventions across Texas.

Prevention Program Grants Active in Fiscal Year 2018

Including the 20 new Prevention Program awards in fiscal year 2018, 86 Prevention Program projects provided programs and services to Texans this year. Of the 86 active projects, 42% focus on primary prevention, 50% on secondary prevention, and 8% on tertiary prevention. A complete list awards by grant recipient for each fiscal year and cumulatively, is available on CPRIT's website at http://grantreports.cprit.texas.gov. CPRIT also provides a searchable database for every CPRIT award at prevention portfolio can be found https://www.cprit.texas.gov/grants-funded.

TABLE 7: PREVENTION AWARDS ACTIVE IN FY 2018 BY GRANT TYPE				
Funding Mechanism	Projects Awarded FY 2018	FY 2018 Award Amount	Projects Active in FY 2018	Total Award Amount
Evidence-Based Cancer Prevention Services	10	$13,257,859	41	$56,333,623
Colorectal Cancer Prevention Coalition	1	$4,034,507	7	$21,795,828
Competitive Continuation/Expansion for Evidence-Based Cancer Prevention Services	--	--	18	$26,301,151
Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations	2	$4,191,199	2	$4,191,199
Cancer Prevention Promotion and Navigation to Clinical Services	--	--	3	$1,179,645
Dissemination of CPRIT-Funded Cancer Control Interventions	3	$894,375	8	$2,393,919
Behavior Change Through Public and Professional Education and Training	--	--	1	$499,907
Tobacco Control and Lung Cancer Screening	4	$5,644,816	6	$8,296,308
Total	**20**	**$28,022,756**	**86**	**$120,991,580**

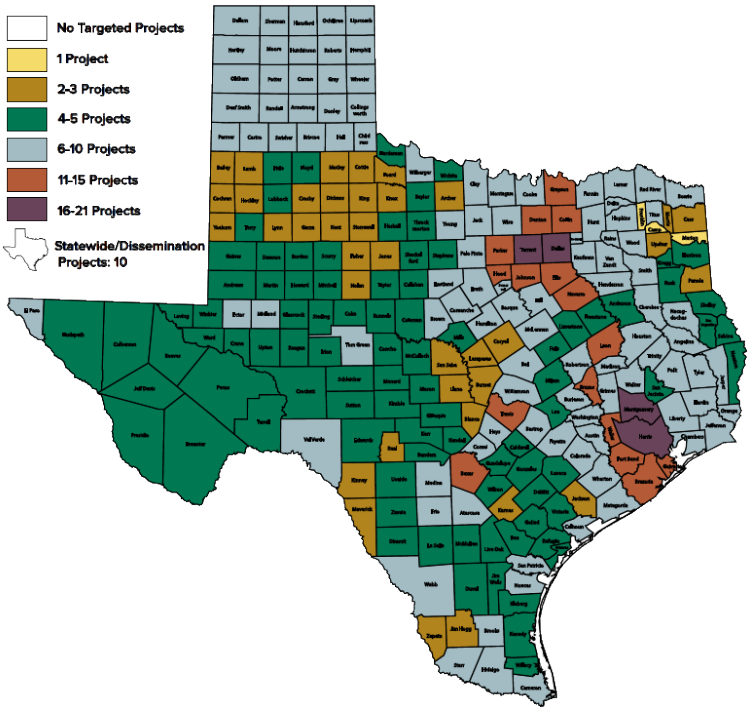
Number of Active Prevention Projects by Cancer Type*



**Some grants address more than one cancer type*

The 86 projects active during fiscal year 2018 reached residents in every county of the state.

Counties of Residence of Populations Served by CPRIT Prevention Projects
86 Active Projects – FY 2018



Representative Prevention Program Grants Awarded in Fiscal Year 2018

PP180016 ***Equitable Access to Lung Cancer Screening and Smoking Cessation Treatment: A Comprehensive Primary Care and Community Health Approach***

Lung cancer is the leading cause of cancer mortality in the U.S., accounting for 1 in 4 cancer deaths. Low-dose computed tomography (LDCT), when combined with multidisciplinary smoking cessation treatments (SCT), serves as an effective strategy to increase survival, improve quality of life, and prevent future lung cancer cases.

Dr. Roger Zoorob at Baylor College of Medicine leads a project to develop and implement a comprehensive primary care and community health program, including provider education, for delivery of LDCT and SCT for high-risk underserved residents of Harris County in 15 community health centers. Prior to the CPRIT project, Harris County had no lung cancer screening programs with integrated SCT services and no providers trained to engage high-risk patients in making shared decisions about the risks and benefits of LDCT screening.

PP180082 ***West Texas HCV Screening and Linkage to Care Program***

Despite improved screening and surveillance guidelines, significant disparities in hepatocellular carcinoma (HCC) remain, disproportionately affecting medically underserved minorities along the Texas-Mexico border. This geographic area has some of the highest HCC mortality rates in Texas, with many of the rural areas lacking basic access to screening services.

This project, led by Patricia Gallegos of Centro San Vicente in El Paso, aims to decrease HCC mortality rates resulting from Hepatitis C virus (HCV) and Hepatitis B virus infections and provide increased access to HCV treatment and survivorship services. The project, which is available to residents living in El Paso, Culberson, Presidio, and Brewster counties, will provide comprehensive patient education and navigation assistance by community health workers,

clinical screening services, as well as professional education and training through Baylor St. Luke's Project ECHO telehealth program.

PP180080 ***HPV Vaccination in a Pediatric Minority-Based Community Oncology Network***

Childhood cancer survivors represent a particularly high-risk population, experiencing significantly higher rates of Human Papilloma virus (HPV)-related malignancies. The HPV Vaccination in a Pediatric Minority-Based Community Oncology Network project, led by Dr. Allison Grimes and Dr. L. Aubree Shay of The University of Texas Health Science Center at Houston, will increase HPV vaccination and series completion rates among eligible childhood cancer survivors (ages 9-26 years) followed by the South Texas Pediatric Minority Underserved NCI Community Oncology Research Program. This is a consortium of five regional pediatric institutions covering 113 counties.

The project includes a continuing education program for providers and staff. The education program is adapted to the unique needs of childhood cancer survivors. Because it is associated with the Children's Oncology Group, the project will inform future survivorship care guidelines and dissemination across oncology centers nationwide.

Prevention Program Highlights

CPRIT's prevention grant awards make it possible for proven cancer prevention strategies and early detection programs and services to reach many more Texans and ultimately decrease the personal and economic burden of cancer statewide.

Barbara J Turner, M.D.

The University of Texas Health Science Center at San Antonio

STOP HCC-Evidence-Based Hepatocellular Cancer Prevention Targeting Hepatitis C Virus Infection

Texas has the second highest incidence of liver cancer in the nation, and the Hepatitis C virus (HCV) infection is the leading cause for the most common type of primary liver. Dr. Turner is building the infrastructure to prevent Hepatocellular Carcinoma (HCC) by redesigning primary care practices in Dallas and South Texas to screen, evaluate, and navigate patients with chronic HCV to treatment. Fifteen clinics across Dallas and South Texas have screened 20,000 baby boomers over the past three years.

Rakhshanda Layeequr Rahman, M.D.

Amarillo Breast Center of Excellence, Texas Tech University Health Sciences Center

Access to Breast and Cervical Care for West Texas (ABC24WT)

The Texas Panhandle is largely comprised of rural medically underserved communities facing ethnic (mainly Hispanic), socio-economic, and geographical barriers that limit access to health care. CPRIT awarded a prevention grant to Dr. Rahman to deliver breast and cervical cancer education, screening, diagnostics, and high-risk counseling services to underserved women in the 26-county region through a strong network of collaborating private and community partners.

Lewis Foxhall, M.D.

The University of Texas MD Anderson Cancer Center

Alliance for Colorectal Cancer Testing (ACT)

CPRIT awarded Dr. Lewis Foxhall a $6.62 million prevention grant to address low colorectal cancer screening rates among medically underserved populations in southeast Texas. The ACT program increases adherence to colorectal cancer screening recommendations in CPRIT's priority populations served through primary care clinics, thus reducing colorectal incidence and mortality disparities.

Last Updated: August 31, 2018

Cancer Prevention & Research Institute of Texas

CPRIT Peer Review, Compliance Program and Conflict of Interest Information

CPRIT PEER REVIEW

Rigorous, independent, merit-based peer review is the foundation for all CPRIT's grant programs and the primary means for ensuring that CPRIT prudently invests the funds committed by Texans in projects with the greatest potential impact on cancer. From CPRIT's inception, the peer review process has included multiple safeguards to address potential conflicts of interest and ensure both fairness and accountability. CPRIT enhanced its processes in fiscal year 2014 pursuant to the recommendations of the State Auditor and the provisions of Senate Bill 149, 83rd Texas Legislature, Regular Session.

CPRIT has followed the lead of organizations such as the National Cancer Institute, the American Cancer Society, the LIVESTRONG Foundation, and Susan G. Komen in establishing a scientific peer review process to vet and score all grant proposals. Scientific peer review provides an objective evaluation of the proposed hypothesis, the methodology to prove the hypothesis, and the prospective findings. Since CPRIT makes awards only to organizations in Texas, it recruits scientific experts who live and work outside of Texas to participate on the peer review panels to reduce any potential conflict of interest between the reviewers and the proposals under review.

In addition to the peer review, CPRIT requires an additional due diligence review of any research proposals received from companies. The due diligence review, performed by outside legal and regulatory experts, assesses the regulatory and commercial path of the proposed development project and underlying scientific discovery. This review is unique to CPRIT among cancer grant-making organizations and is consistent with CPRIT's objective to invest in research and development of discoveries with the highest probability of reaching and benefitting Texans as soon as possible.

CPRIT's three review councils —the Scientific Review Council, Prevention Review Council, and Product Development Review Council — oversee the peer review of all applications submitted to CPRIT. Members of the review councils chair the individual peer review panels within each program area. The councils assess the evaluations completed by the peer review committees and create a final list of proposals recommended for CPRIT grant awards.

The review councils submit their lists of recommendations simultaneously to the presiding officers of the CPRIT Program Integration Committee and the Oversight Committee. The Program Integration Committee meets first to act upon the review councils' proposed awards and develop a final list of recommendations for the Oversight Committee. The Oversight Committee considers the Program Integration Committee's recommendations at a quarterly public meeting; final approval requires a two-thirds vote of the Oversight Committee.

The National Cancer Institute has officially designated CPRIT as an NCI-approved funding entity. This certification involves a comprehensive assessment of CPRIT's peer review process to ensure it conforms to the standards set by the National Institutes of Health, including conflict of interest protections. CPRIT's designation as an NCI-approved funding entity is important because it means that current and potential comprehensive cancer centers in Texas will be able to include CPRIT research grant funding as part of their research base calculations to maintain or earn NCI Cancer Center designations. This enhances Texas' ability to leverage additional federal funding for cancer research and raises Texas' profile as a center for cancer research.

CPRIT Peer Review Processes for CPRIT's Programs

The following tables show the peer review process in effect for the Prevention, Academic Research, and Product Development Research program grants as of the end of fiscal year 2018.

CPRIT's Academic Research Peer Review Process

STEP 1 Request for Application (RFA)	CPRIT releases a Request for Application (RFA) via the website, subscribers to CPRIT's email newsletter and the Texas Register.
STEP 2 Applying Online	Applicants submit proposals using CPRIT's online application receipt system (www.cpritgrants.org). Applicants must include information about all sources of funding, including private investors. Only applications submitted via the designated electronic portal are eligible for consideration of a grant award and applications are eligible only for the grant mechanism under which the grant application was submitted.
STEP 3 Administrative Review	Applications submitted by the deadline are checked for compliance against the application's administrative requirements and may be withdrawn at this step.
STEP 4 Reviewer Conflict of Interest (COI) Identification	Experts and advocates in cancer research are recruited by panel chairs, provisionally appointed by CPRIT's CEO and approved by the Oversight Committee. The reviewers access a non-confidential summary, a list of key personnel and sources of funding for every application. Reviewers flag potential COI. Some categories of COI may excuse a reviewer from reviewing any application submitted under the same grant mechanism.
STEP 5 Reviewer Assignment	Peer reviewers are assigned to panels in their area of expertise. Panel chairs assign applications to primary reviewers (usually 3 per application). At least one advocate reviewer is assigned to each panel. All reviewers live and work outside of the state. A list of members by panel can be found on CPRIT's website. A reviewer with a conflict does not participate in the discussion, presentation, or scoring of the application at any point in the process. Due to volume, research applications may undergo a preliminary evaluation using the process and criteria specified in the RFA.
STEP 6 Initial Scoring	An eligible application undergoes a rigorous peer review; the proposal is evaluated by (usually three) primary reviewers who provide an individual overall score. Individual overall scores are averaged to produce a single initial overall score for the application.
STEP 7 Panel Discussion	The full peer review panel (12-15 reviewers) discusses the applications. If there is insufficient time to discuss all grant applications, the Review Panel chair determines applications to be discussed, based on initial scores. After discussion, each panel member provides individual overall scores that are averaged to provide a final overall score.
STEP 8 Final Scoring	Based upon the discussion and the scores, the peer review panel develops a rank ordered list of applications it recommends for grant awards. A final overall score and a summary statement of the reviewers' comments are provided to each applicant.
STEP 9 Review Council Recommendation	The Scientific Review Council, consisting of the Chair and panel chairs, considers the panels' recommendations and conducts a programmatic review. Criteria considered during programmatic review are spelled out in the RFA. The Council assigns a numerical ranking score to each application. The Council specifies and explains changes, if any, to the applications' goals, objectives, budget or timeline and these are provided to both the CEO and the Oversight Committee (OC). Once the review process is complete, all reviewers sign a statement that they have followed the CPRIT COI agreement terms.
STEP 10 Program Integration Committee (PIC) Review	The Program Integration Committee (PIC) considers the prioritized list of applications submitted by the Program Review Councils and approves by a majority vote a final list of applications to be recommended to the OC. The PIC includes an explanation for its recommendations.
STEP 11 Oversight Committee Action	The CPRIT CEO forwards the PIC's recommendations and provides an affidavit that each application complied with CPRIT's submission and review process. Two-thirds of the Oversight Committee members present and voting must approve each grant award recommendation submitted by the PIC. The CPRIT Compliance Officer also certifies each recommended award.
STEP 12 Grant Award Contract	All CPRIT grants are awarded through a contract that specifies the responsibilities and obligations of the award recipient and reflects certain reporting and legal requirements.

CPRIT's Prevention Peer Review Process

STEP 1 Request for Application (RFA)	CPRIT releases a Request for Application (RFA) via the website, subscribers to CPRIT's email newsletter and the Texas Register.
STEP 2 Applying Online	Applicants submit proposals using CPRIT's online application receipt system (www.cpritgrants.org). Applicants must include information about all sources of funding, including private investors. Only applications submitted via the designated electronic portal are eligible for consideration of a grant award and only for the grant mechanism under which the grant application was submitted.
STEP 3 Administrative Review	Applications submitted by the deadline are checked for compliance against the application's administrative requirements and may be withdrawn at this step.
STEP 4 Reviewer Conflict of Interest (COI) Identification	Experts and advocates in cancer prevention are recruited by panel chairs, provisionally appointed by CPRIT's CEO and approved by the Oversight Committee. The reviewers access a non-confidential summary, a list of key personnel and sources of funding for every application. Reviewers identify which applications match their area of expertise and flag potential COI. Some categories of COI may excuse a reviewer from reviewing any application submitted under the same grant mechanism.
STEP 5 Reviewer Assignment	Peer reviewers are assigned to panels in their area of expertise. At least one advocate reviewer is assigned to each panel. All reviewers live and work outside of the state. A list of members by panel can be found on CPRIT's website. A reviewer with a conflict does not participate in the discussion, presentation, or scoring of the application at any point in the process.
STEP 6 Initial Scoring	An eligible application undergoes a rigorous peer review; the proposal is evaluated by (usually three) primary reviewers who provide an individual overall score. Individual overall scores are averaged to produce a single initial overall score for the application.
STEP 7 Panel Discussion	The full peer review panel (12-15 reviewers) discusses the applications. If there is insufficient time to discuss all grant applications, the Review Panel chair determines applications to be discussed. After discussion, each panel member provides individual overall scores that are averaged to provide a final overall score. A reviewer with a conflict of interest for an application recuses themself from the discussion and scoring of that application.
STEP 8 Final Scoring	Based upon the discussion and the scores, the peer review panel develops a rank ordered list of applications it recommends for grant awards. A final overall score and a summary statement of the reviewers' comments are provided to each applicant.
STEP 9 Review Council Recommendation	The Prevention Review Council, consisting of the Chair and panel chairs, considers the panels' recommendations and conducts a programmatic review. Criteria considered during programmatic review are spelled out in the RFA. The Council assigns a numerical ranking score to each application. The Council specifies and explains changes, if any, to the applications' goals, objectives, budget or timeline and these are provided to both the CEO and the Oversight Committee (OC). Once the review process is complete, all reviewers sign a statement that they have followed the CPRIT COI agreement terms.
STEP 10 Program Integration Committee (PIC) Review	The Program Integration Committee (PIC) considers the prioritized list of applications submitted by the Program Review Councils and approves by a majority vote a final list of applications to be recommended to the OC. The PIC includes an explanation for its recommendations.
STEP 11 Oversight Committee Action	The CPRIT CEO forwards the PIC's recommendations and provides an affidavit that each application complied with CPRIT's submission and review process. Two-thirds of the Oversight Committee members present and voting must approve each grant award recommendation submitted by the PIC. The CPRIT Compliance Officer also certifies each recommended award.
STEP 12 Grant Award Contract	All CPRIT grants are awarded through a contract that specifies the responsibilities and obligations of the award recipient and reflects certain reporting and legal requirements.

CPRIT's Product Development Research Peer Review Process

STEP 1 Request for Application (RFA)	CPRIT releases a Request for Application (RFA) via the website, subscribers to CPRIT's email newsletter and the Texas Register.
STEP 2 Applying Online	Applicants submit proposals using CPRIT's online application receipt system (www.cpritgrants.org). Applicants must include information about all sources of funding, including private investors. Only applications submitted via the designated electronic portal are eligible for consideration of a grant award and only for the grant mechanism under which the grant application was submitted.
STEP 3 Administrative Review	Applications submitted by the deadline are checked for compliance against the application's administrative requirements and may be withdrawn at this step.
STEP 4 Reviewer Conflict of Interest (COI) Identification	Experts and advocates in development of products related to cancer research are recruited by panel chairs, provisionally appointed by CPRIT's CEO and approved by the Oversight Committee. The reviewers access a non-confidential summary, a list of key personnel and sources of funding for every application. Reviewers identify which applications match their area of expertise and flag potential COI. Some categories of COI may excuse a reviewer from reviewing any application submitted under the same grant mechanism.
STEP 5 Reviewer Assignment	Peer reviewers are assigned to panels in their area of expertise. At least one advocate reviewer is assigned to each panel. All reviewers live and work outside of the state. A list of members by panel can be found on CPRIT's website. A reviewer with a conflict does not participate in the discussion, presentation, or scoring of the application at any point in the process.
STEP 6 Individual Evaluation and Scoring	An eligible application undergoes a rigorous peer review; the proposal is evaluated by (usually three or four) primary reviewers who provide an individual overall score. Individual overall scores are averaged to produce a single initial overall score for the application.
STEP 7 Panel Discussion	The full peer review panel (12-15 reviewers) meets by teleconference and discusses the applications. After discussion, the primary reviewers may adjust their initial scores. The primary reviewers' individual overall scores are then averaged to provide an overall evaluation score for the application; the score and a summary statement of the reviewers' comments are generated for each application that does not move forward for further review. A reviewer with a conflict of interest for an application recuses themself from the discussion and scoring of that application.
STEP 8 In Person Presentations	Applicants with sufficiently positive scores after the panel discussion are invited to present their proposal to the full review panel and answer reviewer questions. Following the presentation, the reviewers discuss the application and all reviewers individually submit an overall score for the application. The individual overall scores are then averaged to provide a final overall evaluation score for the application; the score and a summary statement of the reviewers' comments are provided to each applicant. A reviewer with a conflict of interest for an application recuses themself from the discussion and scoring of that application.
STEP 9 Due Diligence Review	The applications that score sufficiently well after the in-person presentation undergo due diligence review conducted by outside contractors hired by CPRIT and overseen by the Chief Product Development Officer. Due diligence involves an in-depth evaluation of the proposal's underlying intellectual property, clinical trial design, regulatory affairs, manufacturability of product, marketing, etc. The due diligence reports are provided to the primary reviewers and the Product Development Review Council for their consideration.
STEP 10 Review Council Recommendation	Following a discussion of the due diligence reports, the Review Council conducts a programmatic review and decides which applications should be recommended for CPRIT grant funding. Criteria considered during programmatic review are spelled out in the RFA. All Product Development applications recommended for grant funding are numerically ranked by the Review Council and submitted to the Program Integration Committee. The Council specifies and explains changes, if any, to the applications' goals, objectives, budget or timeline and these are provided to both the CEO (as Chair of the Program Integration Committee) and the Oversight Committee (OC). Once the review process is complete, all reviewers sign a statement that they have followed the CPRIT COI agreement terms.
STEP 11 Program Integration Committee (PIC) Review	The Program Integration Committee (PIC) considers the prioritized list of applications submitted by the Program Review Councils and approves by a majority vote a final list of applications to be recommended to the OC. The PIC includes an explanation for its recommendations.
STEP 12 Oversight Committee Action	The CPRIT CEO forwards the PIC's recommendations and provides an affidavit that each application complied with CPRIT's submission and review process. Two-thirds of the Oversight Committee members present and voting must approve each grant award recommendation submitted by the PIC. The CPRIT Compliance Officer also certifies each recommended award.
STEP 13 Grant Award Contract	All CPRIT grants are awarded through a contract that specifies the responsibilities and obligations of the award recipient and reflects certain reporting and legal requirements, including revenue sharing terms and agreed upon milestones.

CPRIT COMPLIANCE PROGRAM

The CPRIT compliance program is statutorily mandated to assess and ensure that CPRIT's Oversight Committee members and CPRIT employees comply with applicable laws, rules, and policies. The compliance program also provides fiscal and administrative oversight of all CPRIT grants to ensure compliance with rules, regulations, and laws, as well as internal codes of conduct, policies, and procedures.

CPRIT Employee and Oversight Committee Compliance

One purpose of the compliance program is to ensure that each CPRIT employee and Oversight Committee member complies with reporting and training requirements as provided in state laws, agency rules, and policies. At least annually, all CPRIT employees and Oversight Committee members verify observance of CPRIT's Code of Conduct, complete periodic ethics training, abide by a non-disclosure agreement related to confidential information submitted by grant applicants and grant recipients, and attest that they have no outside employment that conflicts with their CPRIT job or Oversight Committee appointment.

Grant Award Compliance

The compliance program oversees all grants, from the time of application submission through project completion, to verify adherence to agency processes and procedures. The Chief Compliance Officer is responsible for ensuring that all grant proposals comply with the statute and administrative rules before the agency submits the proposals to the Oversight Committee for consideration and approval.

CPRIT documents each step in the application review process through a grant compliance pedigree. CPRIT creates a unique pedigree for each grant application. The compliance pedigree shows the Program Integration Committee and the Oversight Committee that each grant award has met statutory requirements, administrative rules, and CPRIT procedures. The pedigree identifies the actions taken from when CPRIT releases the Request for Applications through the

peer review process, concluding with the Oversight Committee's final decision on the application.

The grant compliance pedigrees and the Chief Compliance Officer's written certification are available in the *Proposed Grant Awards Book* associated with each Oversight Committee meeting. CPRIT posts all Oversight Committee meeting information on its public website.

In fiscal year 2018, the Compliance Program initiated 914 grant compliance pedigrees. The Chief Compliance Officer certified 134 grant proposals for the Oversight Committee's consideration and approval.

Post Award Grant Monitoring

CPRIT's compliance team, led by the Chief Compliance Officer, consists of a compliance program manager and six compliance specialists. This team continuously monitors active grants to ensure that each grant complies with the terms and conditions of its contract and all applicable laws and reporting rules. CPRIT tracks due dates of required grantee reports through an electronic grant reporting and monitoring system.

CPRIT's compliance specialists conduct reviews of grant reimbursements, providing second-level verification that the initial reviews were thorough, consistent, and compliant with CPRIT's statutes, rules, and procedures. In addition to the grant reimbursement reviews, compliance specialists assist with grantee training and technical assistance, support the development of a grantee onboarding and annual training process, and participate in the preventive desk reviews and the on-site review process for current grant recipients.

In fiscal year 2018, the CPRIT Compliance Team performed:

- 258 compliance monitoring reviews (226 desk reviews, 32 on-site reviews);
- 10 grantee training and education events, including annual compliance trainings, new grantee trainings, and trainings for new Authorized Signing Officials. More than 540 grantee staff attended these training opportunities provided to our active grantees;
- 2,200 second-level reviews of grantees' Financial Status Reports (FSRs);
- 40+ single audit and agreed upon procedures reports reviews and worked with five grantees to remediate audit findings; and
- 56 annual compliance attestation reviews and worked with four grantees to remediate deficiencies.

Risk Assessment Model

CPRIT's compliance plan calls for the completion of a comprehensive risk analysis of awarded grants with the goal of determining monitoring coverage, type, priority, recommended staffing, and monitoring schedules for adequate oversight of grant recipients and associated grants. CPRIT first implemented the Risk Assessment Model in fiscal year 2016 and has updated it to reflect monitoring findings from the current fiscal year and recommended changes from CPRIT's internal auditor. The Risk Assessment Model considers several factors in determining grantee risk, including financial exposure, entity maturity, and prior experience administering grants.

CPRIT performs risk assessments on a quarterly and annual basis. Quarterly assessments evaluate new grant recipients that receive funding during the year. Annual assessments provide for ongoing reviews of grant recipients with multi-year awards and those who receive grants over multiple years. Each risk assessment assigns a priority ranking to grant recipients, which helps in determining training and monitoring needs.

Based on the results of the risk assessment, grantees receive a desk review or an onsite monitoring review completed by compliance staff. Compliance monitoring reviews evaluate a grantee's compliance with grant requirements included in Texas Administrative Code Chapters 701-703, Texas Health and Safety Code Chapter 102, CPRIT Policies and Procedures, Uniform Grant Management Standards, and terms of the grant contract.

Fraud, Waste, and Abuse Hotline

CPRIT implemented a compliance and ethics hotline in fiscal year 2015. The hotline is part of the agency's ongoing efforts to ensure that it has strong internal controls to protect the integrity of CPRIT's grant process and to protect state funds. The system allows individuals to report to the Compliance Program any concerns regarding fraudulent activity/theft, misconduct, safety violations, or unethical behavior regarding CPRIT projects or activities. An independent contractor operates the service, which allows users the option to remain anonymous. CPRIT communicates the availability of the hotline to Oversight Committee members, CPRIT staff, and grant applicants and recipients via training, CPRIT's Grant Management System, CPRIT's website, and our mailing list.

Conflict of Interest Information for Fiscal Year 2018

Texas law prohibits any individual involved in making grant award decisions, including peer review panel members, Program Integration Committee members, and the Oversight Committee, from reviewing or voting on an application if the individual has a prohibited conflict of interest. A conflict of interest exists if a reviewer or a close relative of the reviewer has a real or apparent interest in the outcome of an application such that the person may gain financially, professionally, or personally from the approval or disapproval of a grant application. Most often the reviewer's conflict of interest with an application will require the reviewer's recusal only from the discussion and vote on that application. However, there are certain types of conflicts of interest that require the reviewer to recuse him or herself from the discussion and vote on all applications for the same grant mechanism in the same grant cycle.

CPRIT maintains documents that list all conflicts of interest disclosed by reviewers, as well as the steps taken to show that the reviewer recused him or herself from the discussion and vote on the application at issue. This documentation includes a list of reviewers identifying conflicts and sign out sheets reflecting that the reviewer left the room (or the telephone call if CPRIT conducted the review discussion via conference call). CPRIT's third-party grant management contractor maintains the sign out sheet, which an independent third-party contractor reviews separately. CPRIT hires the independent observer to witness peer review meetings and document any deviations from the required process. The independent observer certifies that no reviewer with a conflict of interest in an application participated in the review or vote of that application.

CPRIT relies primarily upon the individual reviewer to identify any conflicts of interest with all applications subject to his or her review. In addition, CPRIT posts the review panel membership on its public website. Doing so allows applicants the opportunity to separately notify CPRIT of any potential conflict of interest risks. CPRIT also has an established process for reporting, investigating, and taking any necessary action for undisclosed conflicts of interest. In fiscal year 2018, there were no allegations of an unreported conflict of interest that CPRIT could confirm after an investigation.

In exceptional circumstances, the participation of a reviewer in the review process outweighs the potential bias posed by a conflict of interest held by the reviewer. CPRIT's statute establishes a process for the Oversight Committee to approve a conflict of interest waiver to allow the otherwise conflicted reviewer to participate in the review process. CPRIT has posted all conflicts of interest requiring recusal in fiscal year 2018 and the supporting documentation, including the conflict of interest waivers approved by the Oversight Committee for fiscal year 2018, on its website at http://coi.cprit.texas.gov.

CPRIT Financials

TABLE 8: FINANCIAL SUMMARY (UNAUDITED) - FOR THE YEAR ENDED AUGUST 31, 2018	
Revenues	
Legislative Appropriations	$297,085,446
License, Fees, and Permits	$416,231
Interest Income	$1,986
Other	$46,755
Total Revenues	**$297,550,418**
Expenses	
Salaries and Wages	$3,876,811
Other Personnel Cost	$838,030
Professional Fees and Services	$9,624,314
Consumable Supplies	$259,314
Utilities	$115,924
Travel	$76,935
Repairs and Maintenance	$11,207
Rent - Machine and Other	$256,485
Printing and Reproduction	$10,204
Other Operating Expenses	$257,003
Grant Payments	$216,527,512
Capital Expenditures	-
Total Expenses	**$231,853,739**
Excess of Revenues Over Expenses	**$65,696,679**

CPRIT's Financial Position

CPRIT's executive management is responsible for establishing and maintaining adequate internal control over financial reporting and compliance with applicable laws, regulations, contracts, and grant agreements, as well as other matters.

McConnell & Jones LLP, a public accounting firm, audited CPRIT's financial statements for the year ending August 31, 2018, ascertaining that the statements "present fairly, in all material respects, the respective financial position of the governmental activities and governmental fund information of CPRIT as of August 31, 2018, and the respective changes in financial position for the year then ended in accordance with U.S. GAAP."

As part of the audit report on the financial statements, McConnell & Jones LLP reviewed CPRIT's internal control over financial reporting and performed tests of CPRIT's compliance with certain provisions of laws, regulations, contracts, and grant agreements to ensure that the statements are free from material misstatements. McConnell & Jones LLP identified no instance of noncompliance or other matter that required reporting under *Government Auditing Standards*.

Planning for the Future

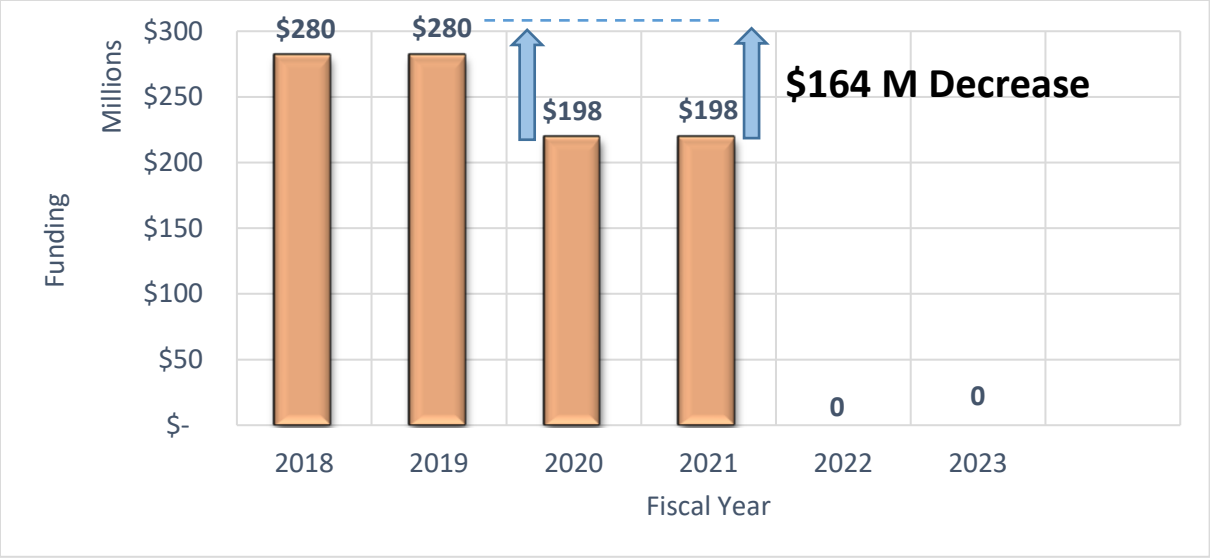
PLANNING

CPRIT's $2.15 billion investment in 1,317 of the best ideas in cancer research, product development and prevention is building a vibrant life sciences and prevention infrastructure across the state and has enhanced Texas' competitive edge in the global fight against cancer. However, the Institute does not have enough money left from its constitutionally authorized $3 billion to fund CPRIT operations and grant awards at its current $300 million per year rate after fiscal year 2019 and unless the legislature acts, CPRIT will cease awarding grants after August 31, 2021. CPRIT staff and the Oversight Committee have engaged in strategic and operational planning over the past several years, exploring opportunities to sustain Texas' competitive edge in the global fight against cancer and addressing near-term and long-range activities necessary for winding down CPRIT's operations, if necessary.

Decreased Funding for Awards in Fiscal Years 2020 - 2022

The declining amount of bond funds available to the agency after fiscal year 2019 means that CPRIT will award fewer grants in fiscal years 2020 – 2022. Over the course of 2018, the Oversight Committee considered several funding allocation scenarios for the remaining bond funds. At a special meeting on January 17, 2018, the Oversight Committee endorsed a plan to distribute the total funds remaining for awards after fiscal year 2019 equally between fiscal years 2020 and 2021, with no awards made after August 31, 2021. Although CPRIT will forgo making awards in fiscal year 2022, the Oversight Committee's plan minimizes operational expenses associated with grant review and maximizes the amount of funds available for awards.

CPRIT's legislative appropriation request for the 2020 – 2021 biennium reflects the Oversight Committee's funding allocation decision. As indicated below, CPRIT's projected grant award budget for the fiscal biennium 2020 - 2021 shows a 29% ($164 million) decrease in award funding compared to the previous biennium. CPRIT has requested an exceptional budget item for $164 million in general revenue to offset the decline in bond funding, which will allow CPRIT to maintain grant funding at current levels for all three CPRIT programs in the 2020-2021 biennium.



Planning for Sunset Review and Cessation of Funding in 2023

CPRIT will undergo sunset review in fiscal year 2023 and the agency is on track to expend all bond funding authority by August 31, 2023. Planning for the possible winding down of operations in 2023 raises the question of what the Texas cancer landscape will look like without CPRIT or a similar entity with enough resources to sustain and capitalize on the momentum Texas has gained in the fight against cancer. Lacking sustained funding to recruit the best cancer research talent and promising new companies to Texas and to support early stage discoveries, translational research activities and Phase I clinical trials, Texas' emerging competitive edge in cancer research and life science industry expansion will dissipate. Without CPRIT, Texans' access to cancer prevention screening and education services in all 254 counties will decrease or end, including those in rural or medically underserved areas of the state.

Financially, an independent economist projects that Texas may expect significant negative economic consequences if CPRIT ceases operations. Even under the assumption that the funds that otherwise would go to CPRIT will be used for other state purposes, the ten-year net cumulative economic effects of not funding CPRIT amount to nearly $142 billion in lost gross product and over 1.2 million lost person-years of employment. These include fiscal losses to Texas state receipts nearing $7 billion and local governments at $3.2 billion.

Even a single year gap in funding has significant consequences. If CPRIT does not issue awards in fiscal year 2022, 320,000 Texans will not have access to lifesaving prevention clinical services in 254 counties as programs dismantle for lack of funding. Advances made for Texas to become the "Third Coast" for biotechnology and biomedical research would be set back. And the state loses $720 million in direct gross product and over 10,000 permanent high-quality jobs.

Planning for Self Sufficiency Is Not A Viable Option for CPRIT's Future

Some have suggested that CPRIT become financially self-sufficient after 2023 by relying upon the state's share of equity and royalty proceeds from CPRIT grant projects to sustain the agency's operations and grant activities. This is not a feasible solution because Texas' portion of grantee profits will not be at a level necessary for many years to serve as a sustainable, predictable funding source. If the state reorients CPRIT's investment strategy to achieve large, near-term returns, it will abandon the statutory reasons for CPRIT's creation and continued existence: expediting innovation in cancer research capabilities across the state and enhancing the potential of breakthroughs in preventions and cures.

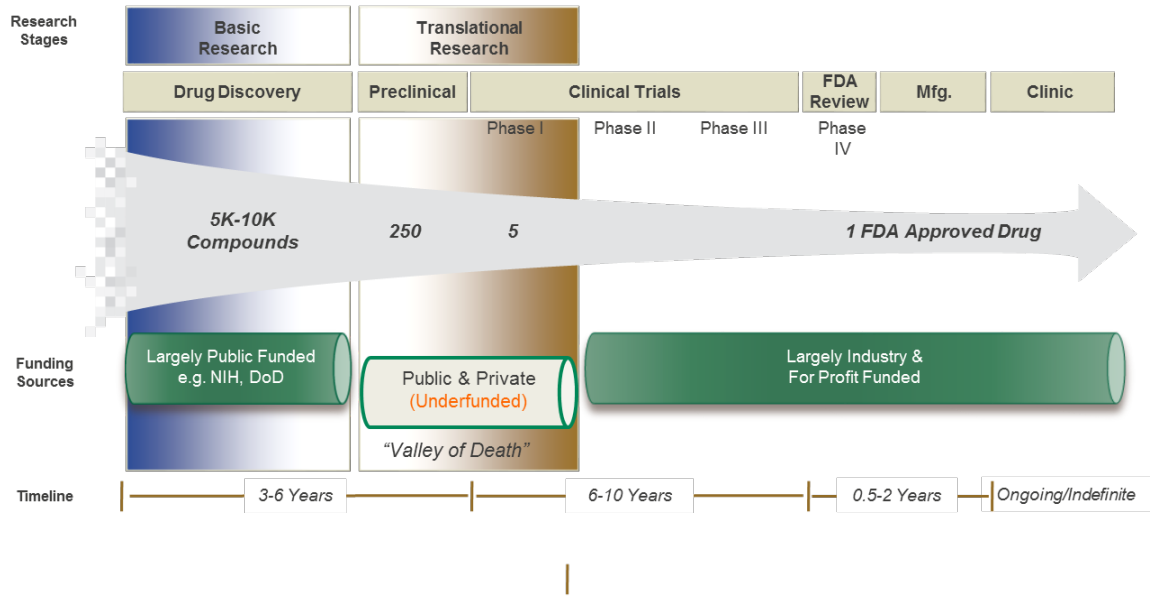
CPRIT's Current Grant Investment Portfolio Focuses on Early-Stage Research

CPRIT's grant investments to date have overwhelmingly been in research that will lead to cancer therapeutics. CPRIT's investment strategy aligns with its statutory purpose, awarding grants to expand research capabilities and support innovations at Texas' higher education institutions and other public and private entities throughout the state. While CPRIT invests 90% of its grant funds in cancer research, CPRIT dedicates the remaining ten percent to projects that make prevention services -- such as evidence-based screenings and educational programs -- available in every county. CPRIT's investments are transformative for the health of Texans and for state's life science infrastructure, but they have not resulted in significant direct revenue payments to the state at this point. CPRIT grantees have paid the state less than $3.5 million in revenue sharing as of August 31, 2018.

To someone unfamiliar with the timeline and stages of the cancer drug development process, it may seem like CPRIT's *de minimis* revenue sharing return eight years after its first awards is indicative of poor award decisions. This is incorrect - it is far too soon for most of CPRIT's

projects to be at a point where they are selling a product. While all CPRIT grant contracts include a provision requiring grantees to share a portion of the revenue generated from the successful drug, device, or diagnostic developed with CPRIT funding, the CPRIT- supported product must traverse the entire development continuum before the state receives any revenue. As depicted below, that process begins with a scientist's discovery in the laboratory through preclinical and animal testing, clinical testing, and regulatory approval.

Drug Development Life Cycle



Long development cycles (15+ years on average) and high attrition rates characterize the drug development process, with large returns for the few projects that successfully navigate the regulatory gamut. The history behind the 2018 Nobel Prize-winning cancer immunotherapy treatment is a good example of the extended regulatory process drug developers must pass through to bring a promising laboratory finding to market. CPRIT Scholar Dr. James Allison's breakthrough discovery -- identifying an antibody that blocked the "checkpoint" protein on T-cells, unleashing the body's immune system to attack tumors -- came to light in the 1990s. The first checkpoint inhibitor drug, Ipilimumab (known commercially as Yervoy) was not available for the treatment of late-stage melanoma until 2011. In the years in between, drug developers contracted with hospitals and clinics to participate in clinical trials of Ipilimumab, enrolled patients fitting precise requirements, tracked patients' health while taking the drug, ensured the

Ipilimumab was dosed appropriately, and analyzed reams of data, all while working closely with regulatory officials at every step of the process. Today there are lifesaving immunotherapy drugs on the market treating lymphoma, lung, renal, and other forms of cancer, as well as thousands of clinical trials investigating new therapies stemming from Dr. Allison's initial laboratory breakthrough. Yet, even a revolutionary discovery like Dr. Allison's checkpoint inhibitor required 15 years for the idea to become a drug available to patients and generate revenue. Given the innovative cancer research work CPRIT is supporting right now, Texas may be funding the next breakthrough in cancer treatment now but the state will not see returns for another decade.

Investing for Self Sufficiency Will Re-Orient CPRIT Away from Its Statutory Purpose and Texas' Unique Role in Supporting Breakthrough Cancer Research and Prevention

If CPRIT funds its future operations and grant activities solely with grantees' revenue sharing payments, then the agency must reposition its grant portfolio significantly. Redirecting CPRIT's investment strategy to maximize revenue generation will result in CPRIT devoting its grant awards to exclusively late-stage product development research projects that are close to market approval. Given the targeted development stage, it is likely that CPRIT would award these grants to large out-of-state pharmaceutical companies, with the state's share of revenues consisting of stock purchases.

While the reorientation may result in near-term revenue generation, CPRIT's investments would only be additive, rather than transformative, to the pharmaceutical companies receiving the state's money. Repositioning CPRIT's portfolio for self-sufficiency also results in CPRIT potentially displacing other existing sources of private capital. As depicted by the *Drug Development Life Cycle* graphic, the market typically invests in later stages of drug development (late stage Phase II - Phase IV clinical trials) and manufacturing, after the potential treatment has successfully cleared early regulatory hurdles.

Historically, government, and to a lesser extent, private donors and non-profit foundations, support vital basic research through grants. Venture capital and pharmaceutical companies are far less likely to fund the basic research sparking big, innovative ideas that serve as the foundation for tomorrow's groundbreaking drugs. CPRIT Scholar Dr. James Allison, when discussing his 2018 Nobel Prize in Medicine, credited basic science for its critical role as "the fundamental foundation

for major advances in medical treatment…[W]ithout that early funding of basic science from the government, many of the therapies that currently treat millions of cancer patients worldwide simply wouldn't exist."

CPRIT's new portfolio would not contribute toward strengthening the state's emerging biotechnology and cancer prevention infrastructure and would have no effect on enhancing the increasing research prominence of Texas' institutions of higher education. CPRIT-funded cancer prevention screenings and educational services that serve all counties in Texas will cease. Given this, if Texas' sole goal is to increase near-term investment returns, it is not necessary for CPRIT to exist.

Revenue Sharing Payments are Already Committed to Paying for Debt Service

CPRIT notes that the Legislature established an interest and sinking fund in 2013 consisting of the patent, royalty, license fees, and other contractual income. The legislative purpose of the interest and sinking fund is to pay for the debt service on CPRIT's bonds. To the extent that the Legislature wishes to redirect the state's portion of revenues in support of CPRIT's future operations and activities, there may be no mechanism to appropriate these proceeds to CPRIT if the Institute is no longer a state agency. CPRIT is unaware of precedent for the state to dedicate state revenues to support a private entity.

Operational Issues to Plan for if CPRIT Sunsets in 2023

CPRIT staff and the Oversight Committee use an operational planning process to categorize necessary steps leading up to CPRIT's scheduled sunset review in 2023. If the agency does not continue operations after August 31, 2023, CPRIT has identified three significant issues that CPRIT and the state should address and prepare for during the sunsetting process. CPRIT will work with stakeholders to refine the issues, described below, and devise action plans leading up to sunset review.

Monitoring On-going Grant Projects

CPRIT grant projects typically last two to five years. CPRIT's statute authorizes the Oversight Committee to award grants through August 31, 2022. Unless CPRIT severely truncates project

timelines, which will affect the grantee's ability to complete project work, many CPRIT grant projects will continue to be active beyond CPRIT's sunset date. These grant projects will require continued specialized monitoring to protect the state's interests and assure that grantees are meeting contractual requirements. Grant management and compliance will require some combination of state employees and/or contracted personnel.

Drawing Down Bond Proceeds

In addition to monitoring active grants, a future entity must issue bonds after August 31, 2023, to support ongoing grant cost reimbursement. CPRIT reimburses approved grant project costs incurred by the grantee for the previous fiscal quarter. Because the state issues CPRIT bonds on an as-needed basis, this lengthy fiscal review and draw down process affects when the state issues debt to cover approved disbursements. Although CPRIT plans to fully commit the $3 billion in bond proceeds prior to the agency's sunset, some portion of the bonds will remain for the state to issue for grant disbursements. The statute limits the amount of CPRIT bonds that the state may issue each year to no more than $300 million. It is unlikely that CPRIT will draw down all grant authority by 2023, even if the state started issuing the full $300 million annually (rather than on an as-needed basis) and advancing funds to grantees in place of reimbursements. It is prudent for the state to plan for staff and resources necessary to monitor the drawdown of grant funds post 2023 and coordinate with the Texas Public Finance Authority and the Bond Review Board.

Ensuring the State Receives Contractually Required Revenue Sharing Payments

Revenue sharing obligations owed by grantees will require ongoing monitoring of all CPRIT grants regardless of whether the grant projects are active or closed. Every CPRIT grant contract includes terms ensuring that the state benefits monetarily if a grant project generates revenue. Given the long drug development life cycle, CPRIT expects that the state will realize the largest portion of the grantee's revenue sharing obligations after August 31, 2023. Over the next several years, grantees will license more intellectual property and more CPRIT-funded products will reach the market as the projects move further through the regulatory and development process.

Legislation passed in the 85th Legislative Session authorizes CPRIT to transfer the management of equity and royalty assets generated by CPRIT's revenue sharing agreement to the Texas

CPRIT's Revenue Sharing Terms

Every CPRIT grant contract includes conditions ensuring that the state benefits monetarily if a grant project generates revenue. The revenue sharing terms provide a fair and reasonable yield on the state's investment while accounting for CPRIT's statutory mission to accelerate development of cancer treatments and cures and stimulate company formation and job growth in Texas. The statute directs CPRIT to balance the state's opportunity to benefit through revenue sharing while avoiding onerous terms that stop further development of the CPRIT-funded project.

- CPRIT Academic Research Program and Prevention Program grant contracts with institutions and non-profit community organizations require the grantee to pay CPRIT 10% of the revenue received by the institution or organization. Revenue sharing terms for Product Development Research Program grants are more structured.
- Almost all revenue sharing agreements included in the CPRIT company award contracts are royalty-based, requiring payments until the grantee has paid some multiple (typically 2X – 4X) of the grant award. Most agreements also include a smaller ongoing royalty obligation. CPRIT does not require milestone or other pre-revenue payments that may weaken a company's cash position prior to getting a product in the marketplace. In a few instances, CPRIT's revenue sharing is in the form of equity ownership.

Treasury Safekeeping Trust Company. An ongoing monitoring system to track CPRIT's grant investments is necessary to ensure that grantees are fulfilling their contractual obligations and to protect potential state assets. The tracking system should monitor CPRIT-funded projects at both academic institutions and public/private companies. CPRIT will work with the Trust Company to establish an effective monitoring system and a smooth transition of equity and royalty contracts.

Cancer Prevention & Research
Institute of Texas